DISSERTATION ON

A STUDY TO IDENTIFY PRE MALIGNANT CHANGES IN ORAL MUCOSA AMONG TOBACCO CHEWERS BY TOLUDINE BLUE TEST IN MEDICAL WARDS AT RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI -03

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CERTIFICATE

This is to certify that this dissertation titled **"A Study to identify pre malignant changes in oral mucosa among tobacco chewers by Toludine Blue Test in medical wards at Rajiv Gandhi Government General Hospital, Chennai -03"** is a bonafide work done by **Mrs.R.RAMA,** College of Nursing, Madras Medical College Chennai-03, and submitted to The Tamilnadu Dr.M.G.R. Medical University, Chennai in a partial fulfillment of the University rules and regulations towards the award of the degree of Master Science in Nursing Branch I, Medical Surgical Nursing under our guidance and supervision during the academic period (2012 – 2014).

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ABSTRACT

Oral cancer is both preventable and a curable disease. Preventable, because the pre malignant stage can be detected by screening and curable because the very early stage can be cured. It is the commonest cancer among people. The incidence and mortality from this disease in developing countries is very high, because of the unavailability of organized screening programmes. The objective of the investigator is to identify the factors of oral cancer, to identify the pre malignant changes in oral mucosa among tobacco chewers by toludine blue test and to associate the relationship with the demographic variables. The investigator interviewed and examined 60 subjects through structured questionnaire in English. The toludine blue test to identify the pre malignant changes in oral mucosa was found to be highly sensitive and can be performed by not only physician but also other trained health care providers. Among the 60 people seen by vital staining, 50% of them were found positive by chi square test and referred to the concerned department for further management. The role of a nurse in interacting with the tobacco chewers and the results of the study had given ideas that certain factors such as smoking, chewing, alcohol use, pan parag, gutkha, hans, plays a vital role in the occurrence of pre malignant changes in the oral mucosa. From this study it was concluded that some factors associated with the occurrence of the pre malignant changes of the oral mucosa and also it is obvious that the low cost methods for oral cancer prevention do have a vital role in reducing the incidence of oral cancer.

CHAPTER - I

INTRODUCTION

" I Keep six honest serving men, they taught me all I know. Their names are what, why, when, how, where and who"

-Rudyard kipling

Cancer is not a single disease with a single cause; rather it is a group of distinct diseases with different causes, manifestations, treatments, and prognoses. More than two million people are diagnosed each year with cancer, affecting one of various body sites. Cancer is a leading cause of death next to the cardio vascular disease which is the predominant for mortality in India. Although the numbers of cancer deaths have decreased slightly, more than 560,000 people were expected to die from a malignant process. Cancer can be considered a chronic disease requiring ongoing management, rather than a terminal illness. It consists of more than 100 different conditions characterised by uncontrolled growth and spread of abnormal cells. Normal mechanisms of growth and proliferation are disturbed which results in distinctive morphologic alterations of the cell and aberrations in tissue patterns.

The malignant cells is able to invade the surrounding tissue and regional lymph nodes. Primary cancer usually has a predictable natural history and pattern of spread.

Metastasis is the secondary growth of the primary cancer in another organ. The cancer cells migrates through a series of steps to another area of the body. Most patients die as a result of metastases rather than progression of the primary cancer. Metastasis begins with local invasion followed by detachment of cancer cells that disseminate via the lymphatics and blood vessels and eventually establish a secondary tumour in another area of the body. Lymph nodes are often the first site of distant spread.

The relative frequency of oral cancer in Asia is higher compared to other cancers, but its importance lies in its reported high mortality. Infact, approximately 50% of patients with oral cancer will die within 5 years mainly because of delay in diagnosis. Neverthless, if oral cancer is diagnosed during stage I, the survival rate improves to 86%.

In the oral cavity, there are numerous mucosal disorders designated as potentially malignant, whose diagnosis and treatment may favour early detection or prevention of cancer thereby diminishing its incidence and mortality.

There is no agreement regarding the efficacy of conventional oral examination in the detection of potentially malignant disorders and early oral cancers. There are several tests and adjunctive diagnostic techniques that are now commercially positive staining correlated with clinico pathologic. Oral health is essential in improving one's quality of life. Any abnormality ranging from dental decay to fatal oral cancer affects individuals well being.

Tobacco usage has become a major health problem. While there are many forms of tobacco product, especially tobacco chewing, hans, gutka, pan parag.

Tobacco pyrolysis produces tobacco containing by products and free radicals which are carcinogenic. They act by disruption of normal cellular and molecular mechanisms Oral cancer may occur on the lips or anywhere within the mouth [eg: tongue, floor of the mouth, buccal mucosa, soft palate, hard palate, pharyngeal walls, and tonsils]. Oral cancer is the most common cancer in Indian males. It accounts for 50% to 70% of total cancer mortality.The incidence is nearly 11% in males and 5% in females. It is more common in men (male- to-female ratio of 2:1). Mortality rates have been decreasing since the early 1980s. The 5-year

survival rate for all stages of cancer of the oral cavity and pharynx combined is 53% , and the 10-year rate is 43%.

Although the definitive cause of oral cancer is unknown, there are a number of predisposing factors. Factors that influence the development of oral cancer include tobacco use (e.g. Gutka, tobacco chewing, cigar, cigarette, pipe, snuff), excessive alcohol intake, and chronic irritation such as from a jagged tooth or poor dental care.

In the modern world due to the advancement of science and technology, the life expectancy of the population has increased. A great number of the people are living to older are at risk to chronic diseases , cancer is the fearful and dreadful disease for several reasons.

Cancer , the very utterance of the word sends down a shiver to our spine. It spells agony despair gloom and death. Cancer is curable and there is life after cancer. In the light of present knowledge, early detection and prompt treatment of cancer and pre- cancerous conditions provide the best possible protection against the cancer for the individual and the community.

Cancer is today not a mysterious killer as was earlier because its evolution can be recognized even before it strikes. The early warning signs are often vague and common to all other illness. If public learn to recognize in the earliest stage and seek doctor's advice , they may save themselves. [Indian cancer society_2005].

Despite of public importance, there is no effective prevention programme in most developing countries and the risk of disease and death due to oral cancer remains largely uncontrolled. Invasive cancer is preceded by a long phase of precancerous lesions that can be detected by simple treatment which prevents the invasive cancer.

1.1 NEED FOR THE STUDY

Oral health is essential in improving one's quality of life. Any abnormality ranging from dental decay to fatal oral cancer affects individual's well being. Oral cancer is a significant threat to the public health as is often not diagnosed until it is advanced.

Tobacco usage has become a major health problem. While there are many forms of tobacco product, most common is the manufactured cigarette, hans, gutka, pan parag. They act by disruption of normal cellular and molecular mechanisms.

Despite advances in detection and treatment of oral cancer, the overall survival rate is less than 50%. Oral cancer when detected at an early stage is often curable, inexpensive to treat and affords a better quality of life.

Various methods have been developed to supplement clinical examination and to improve diagnosis of oral cancer in its early stage. The most evaluated adjunct for lesion detection is toludine blue, a metachromatic acidophilic dye. Dysplasia in premalignant lesions contains much more DNA and RNA than the normal epithelium due to active cellular proliferation. So use of in vivo staining by means of toludine blue is based on the fact that it selectively stains acidic tissue components such as DNA and RNA. Oral lesions stained with toludine blue showed consistent loss of chromosomal genetic information, termed loss of heterozygosity.

Previous studies showed that sensitivity and specificity of toludine blue were quite reliable in revealing early oral premalignant lesions and monitoring recurrences of oral cancer. Toludine blue positive staining correlated with clinicopathologic risk factors and high risk molecular patterns.

A question needs to be answered is whether toludine blue can be used to screen premalignant lesions occurring in tobacco chewers.

Cytological study of oral cells is a non invasive technique that is well accepted by the patient, and therefore a better option for early diagnosis of potentially malignant lesions in tobacco chewers.1% toludine blue is used to detect dysplasia and cytological changes in oral smears.

Many studies with toludine blue used Papanicoloau kit for staining smears. Studies carried out showed that toludine blue enhanced the staining characters of pap stain by improving cytological features and stain quality. However little attention has been given to the effect of different staining procedures in toludine blue application.

Aim of the present study is to assess the smears before and after application of toludine blue in tobacco chewers. Toludine blue (also known as tolonium chloride) is a vital dye that may stain nucleic acids and abnormal tissues. It has been used for decades as an aid to the identification of mucosal abnormalities of the cervix as well as in the oral cavity. It has been valued by surgeons as a useful way of demarcating the extent of a lesion prior to excision. While not currently approved by the FDA for us as an oral cancer screening technique in the United States, toludine blue has been championed in other parts of the world for several decades as a means of identifying clinically occult lesions inpatients whose oral mucosa may otherwise be normal – this, as a screening test or adjunct. Various attempts to clinically highlight probable dysplastic areas before biopsy have, unfortunately, not proven to be absolutely reliable but may be of some help where there is widespread "field change" such as seen in patients at high risk for oro pharyngeal squamous cell carcinoma[OSCC]. Toludine blue (TB) staining is a simple and inexpensive diagnostic tool that uses a blue dye

to highlight abnormal areas of mucosa. TB is a basic metachromatic nuclear stain which stains nuclear material of malignant lesions and PML but not normal mucosa, used by (a) the patient rinsing the mouth with 1% acetic acid for 20 seconds followed by a similar rinse with water twice for 20 seconds; (b) rinsing the mouth with 5-10 cc. 1% toludine blue solution; and (c) rinsing with 1% acetic acid solution (5 oz.) for about 1 minute followed by a water rinse. In the highest risk population, prior upper autodigestive tract cancer patients, TB has a higher sensitivity to detect carcinoma *in situ* (CIS) and OSCC when compared to a COE (96.7% and 40%, respectively). False positive staining (when lesions stain blue, but no carcinoma is identified after a biopsy is taken) occurred in 8-10% of cases associated with keratotic lesions and the regenerating edges of ulcers and erosions. Here, the probability of a false negative finding for invasive OSCC is low and the absolute number of false positive tests is expected to be reduced. The clinical appearance of a dark royal blue stain may be significantly related to the nuclear uptake of TB, compared to pale royal blue staining which may be unrelated to any histological feature. Studies assessing TB have shown a sensitivity and specificity ranging from 93.5 to 97.8% and 73.3 to 92.9%, respectively. TB staining may identify high-risk oral PMLs with poor outcome and positive TB staining may be related to genetic changes [allelic loss or loss of heterozygozity (LOH)] associated with progression to OSCC even in histologically benign lesions and lesions with mild dysplasia. TB may also help pre-operatively; in one reported case of OSCC, there were malignant or pre-malignant cells more than 1 cm away, requiring a resection of a size that would not have been addressed during COE alone, though, from the discussion above, it can be seen that even mucosa of a normal appearance might be expected to contain molecular changes of early carcinogenesis.

1.2 STATEMENT OF THE PROBLEM

A study to identify the Pre-malignant changes in Oral Mucosa among Tobacco Chewers by Toludine Blue test in Medical Wards at Rajiv Gandhi Government General Hospital , Chennai-03".

1.3 OBJECTIVES

1. To identify the changes in oral mucosa among tobacco chewers.
2. To assess the oral mucosa after the application of toludine blue among tobacco chewers.
3. To compare the effectiveness of changes in oral mucosa before and after the application of toludine blue among tobacco chewers.
4. To find out the association between the selected demographic variables and the effectiveness of toludine blue among tobacco chewers.

1.4 OPERATIONAL DEFINITION

Identify

Able to recognize something which can be distinguish from other.

Premalignant

A premalignant is a condition occurring before the onset of malignancy in more number of patients.

Oral Mucosa

Is the mucous membrane epithelium of the mouth.

Toludine Blue

Is a dye which stains the mucous membrane.

Tobacco Chewers

Individual having habit of chewing tobacco.

1.5 HYPOTHESIS

H-1 : People have poor knowledge regarding oral cancer and cancer prevention programme.

H-2: There will be a significant association between the selected demographic variables and the risk factors.

1.6 ASSUMPTIONS

1. Oral cancer is the commonest cancer among south Asians and tobacco chewers.
2. It is assumed that tobacco chewers may have inadequate knowledge regarding pre malignant changes.
3. Early identification and appropriate management will prevent the mortality and morbidity due to oral cancer among tobacco chewers.
4. Screening helps the tobacco chewers to detect cancer by simple method at an earlier stage.
5. Health education will bring about positive lifestyle practices towards prevention of oral cancer.

CHAPTER -II

"Literature is the human activity that takes the fullest and most precise account of variousness , possibility , complexity and difficulty.

-Lionel Trilling.

REVIEW OF LITERATURE

The review of literature is a critical summary of research on a topic of interest, often prepared to put a research problem in context [polit 2004]

A literature review is a critical and in- depth evaluation of the previous related research . Literature review aids in familiarizing the researcher with the existing knowledge base and develop an understanding of the conceptual framework , related studies with occurrence of oral cancer among the male and female aged between 18 - 60years. Review of literature thus provides a knowledge base for proceeding research.

2.1 REVIEW OF RELATED STUDIES

PART 1: Literature related to knowledge and awarenes regarding cancer screening

PART 2: Literature related to visual inspection of oral mucosa using acetic acid and toludine blue.

PART 1: Literature Related To Knowledge And Awareness Regarding Oral Cancer Screening

Mishra G. et. al.,(2011) had conducted a study to determine cancer awareness among men and women of low socioeconomic status in Mumbai slums.Data of consenting participants , collected using structured questonarrie, was differentiated into good and poor level of

awareness using point based grading procedure. The study concluded that cancer creating awareness about screening, its availability, and motivating the general population for screening is necessary.

Cancer link Trustee Board (1998) carried out a project in London and studied the knowledge and opinions of men and women regarding their awareness about screening services for oral mucosal cancer. 194 men and women completed questionnaires and the result showed that they were unaware of the screening services. Many others held misconceptions about the smear test and fear, embrassment and previous negative experiences all inhibited initial or repeat attendance for screening.

PART II: LITERATURE RELATED TO VISUAL INSPECTION OF THE ORAL MUCOSA USING ACETIC ACID AND TOLUDINE BLUE

Rahman F TIPPU SR et.al.(2012) Department of oral pathology and microbiology jaipurThe study included 86 participants suspected of having oral premalignant lesions or oral squamous cell carcinoma. One percent toludine blue was applied to the lesions, followed by cytology. A biopsy was then performed on the tissue. Histopathologically proven oralpremalignant lesions/oral squamous cell carcinoma lesions were analyzed for sensitivity, specificity, postive predictive value, and negative predictive value of both screening techniques. The association of screening techniques and histopathologic diagnosis among the oral premalignant lesions, oralsquamous cell carcinoma, and benign groups were analyzed using the Fisher exact test. $P < .05$ was considered significant

Toby steele et.al. (2011) The purpose of this study was to evaluate the efficacy of the toludine blue (TB) test as a diagnostic tool in the detection of malignant and dysplastic lesions of the oral cavity. This study was carried out because of a lack of consensus among different

authors on the utility of TB, as well as to determine useful adjuncts to detect oral pre-cancer and cancer. The study included 160patients with oral mucosal disorders that included suspicious or malignant lesions detected at clinical visual examination, confirmed by histopathological evaluation.

Upadyay J, Rao NN,(2011) Department of oral pathology, Mathura, India Toludine blue stain is used as a marker to differentiate lesions at high risk of progression in order to improve early diagnosis of oropharyngeal carcinomas. This study focused on 45 oral mucosal lesions in 32 patients (13 female, 19 male). In 9 cases, multiple biopsies were collected. Of the 45 lesions examined, 26 (57.0%) were defined clinically benign, while 19 (42.3%) were defined as suspected lesions (premalignant or malignant). According to the clinical examination, the sensitivity was 53% (16/30) and for toludine blue staining 96.2% (26/27) (p = 0.0007). The specificity was 80% (12/15) for clinical examination and 77.7% (14/15) for toludine blue staining (p = 0.79). In conclusion toludine blue stain has been shown to be a reliable aid when clinical examination is unable to differentiate lesions at high risk of progression and then it improves early diagnosis for oral cavity and oropharyngeal cancer.

Onofre MA et.al.(2010) The objective of this study was to evaluate the reliability of in vivo staining with toludine blue in the detection of oral epithelial dysplasia, in situ carcinoma, and invasive squamous cell carcinomas in potentially malignant epithelial lesions (PMELs) and superficial oral ulcerations suggesting malignancy.

Fifty patients with PMELs and superficial oral ulcerations suggestive of malignancy were selected from those treated at the OralMedicine Service, Faculty of Dentistry, Araraquara, Brazil. All lesions were submitted to staining with an aqueous solution of 1% toludine blue, followed by biopsy

and histologic analysis. The sensitivity, specificity, and positive and negative predictive values were calculated.

Histologic diagnosis revealed that 14% of the lesions analyzed were in situ carcinoma and invasive squamous cell carcinomas, 12% were epithelial dysplasias, 13% were keratosis, 40% were lichen planus, and 8% were other benign lesions. The sensitivity of the staining was 77%, the specificity 67%, and the positive and negative predictive values 43.5% and 88.9%, respectively.

Staining with toludine blue was demonstrated to be highly reliable in the detection of in situ carcinoma and invasive squamous cell carcinoma, because false-negative results for the lesions did not occur. Toludine blue staining is an adjunct to clinical judgment and not a substitute for either judgment or biopsy.

Vacher C , Legens M, Rueff B, LezyJP (2009) Early diagnosis of oral carcinomas allows a limitation of functional consequences of surgical treatment. A prospective study was designed in 270 alcoholic patients. We practiced a clinical examination of the oral cavity by a stomatologist followed by a Toluidin blue test. The clinical examination permitted to detect 1 carcinoma and 23 leukoplakias. The Toluidin blue test revealed one more carcinoma and two leukoplakias more. The early diagnosis of oral carcinomas in alcoholics patients gives them a better survival. The Toluidin blue test could be proposed as an aid to early diagnosis of these carcinomas.

Patton L.L et.al (2009) studies that assessed the diagnostic accuracy of vital tissue staining with toludine blue , visualisation adjuncts (viziLite, Microlux DL, Orascoptic DK, VEL scope), toludine blue staining and vizilite (chemoluminescent light detection system) in combination , or cytopathology (Oral CDx brush test system) for the detection of premalignant and malignant lesions were eligible for inclusion. Included

studies were required to use histological confirmation of tissue biopsy as the reference standard and to report sufficient data to calculate measures of diagnostic accuracy. In most included studies, patients had suspicious oral lesions or a history of oral cancer, but some had known current oral cancer. Limited study details and results were reported in an online supplement , including details of adjunctive tests used , and in the case of visualisation adjuncts, operator details.

Allegra E , Lombardo N, Puzzo L, Garozzo A(2009) Toludine blue stain is used as a marker to differentiate lesions at high risk of progression in order to improve early diagnosis of oropharyngeal carcinomas. This study focused on 45 oral mucosal lesions in 32 patients (13 female, 19 male). In 9 cases, multiple biopsies were collected. Of the 45 lesions examined, 26 (57.0%) were defined clinically benign, while 19 (42.3%) were defined as suspected lesions (premalignant or malignant). According to the clinical examination, the sensitivity was 53% (16/30) and for toludine blue staining 96.2% (26/27) (p = 0.0007). The specificity was 80% (12/15) for clinical examination and 77.7% (14/15) for toludine blue staining (p = 0.79). In conclusion toludine blue stain has been shown to be a reliable aid when clinical examination is unable to differentiate lesions at high risk of progression and then it improves early diagnosis for oral cavity and oropharyngeal cancer.

Fedele S (2009) The World Health Organization has clearly identified prevention and early detection as major objectives in the control of the oral cancer burden worldwide. At the present time, screening of oral cancer and its pre-invasive intra-epithelial stages, as well as its early detection, is still largely based on visual examination of the mouth. There is strong available evidence to suggest that visual inspection of the oral mucosa is effective in reducing mortality from oral cancer in individuals exposed to risk factors. Simple visual examination, however, is well known to be limited by subjective

interpretation and by the potential, albeit rare, occurrence of dysplasia and early OSCC within areas of normal-looking oral mucosa. As a consequence, adjunctive techniques have been suggested to increase our ability to differentiate between benign abnormalities and dysplastic/malignant changes as well as to identify areas of dysplasia/ early OSCC that are not visible to naked eye. These include the use oftoludine blue, brush biopsy, chemiluminescence and tissue autofluorescence. The present paper reviews the evidence supporting the efficacy of the aforementioned techniques in improving the identification of dysplastic/malignant changes of the oral mucosa. We conclude that available studies have shown promising results, but strong evidence to support the use of oral cancer diagnostic aids is still lacking. Further research with clear objectives, well-defined population cohorts, and sound methodology is strongly required.

All lesions were submitted to TB staining. The sensitivity and specificity for the detection of malignant or dysplastic lesions by this test were65.5% and 73.3%, respectively. Overall, the detection ratewith TB (sensitivity) was slightly lower compared withthose reported by other authors but the specificity was comparable to several reports. Positive predictive value(35.2%) was also lower than previous studies, where as negative predictive value (90.6%) was similar. The simplicity of the test procedure and the validity of derived values suggest TB staining can be a valuable adjunct to the diagnostic process, as long asit is carefully correlated with the clinical characteristics of.the mucosal disorder and histopathological diagnosis.

Scully et.al.(2008) had conducted a study conventional oral examination is the standard method of revealing pre malignant lesion and oral squamous cell carcinoma, confirming the clinical suspicion by biopsy and histopathological examination.Most cancers of the oral cavity are oral squamous cell carcinomas [oscc], and tobacco, alcohol

and betel use the main factors for these and many potentially malignant lesions(PML).The main high risk groups are older adult males and females who use tobacco and alcohol.

Nagaraju, et.al.(2008) has done a study of the 60 cases (30 cases of pre malignant and 30 malignant lesions), both the stains were retained in 52 cases whereas four cases of malignant lesions of poorly differentiated squamous cell carcinoma and one case of moderately differentiated squamous cell carcinoma and two cases of premalignant lesions(erosive lichen planus) failed to retain both the stains while one case failed to retain toludine blue stain of the premalignant lesions, 15[50%], 12[40%] and three [10%] lesions comprised of homogenous leukoplakia, speckled leukoplakia and erosive lichen planus , respectively.

Epstein JB et.al (2007) Toludine blue (TB) has been shown to aid in the detection and diagnosis of oropharyngeal squamous cell carcinoma (OSCC)and oral premalignantlesions (OPLs). TB has been shown to enhance visualization of oral lesions and assist in identifying sites of increased risk of dysplastic/malignant change and promote biopsy. TB has been shown to identify lesions with molecular changes associated with risk of progression of OPLs to OSCC. A recent prospective longitudinal study showed TB retention in histologic benign lesions and lesions with mild dysplasia that are at increased risk of progression to cancer. Clinical trials show that TB is useful in identifying asymptomatic OSCC and premalignant lesions at risk of progressing to SCC, which might otherwise be undetected until lesions become more advanced. The data supports TB use in oral examination of patients at risk of OSCC.

Drimel O et. al. (2007) Improvement of survival rate and quality of life after treatment of oral squamous cell carcinoma as well as cost reduction requires reliable early diagnosis of the tumor and its precursor lesions. Four different screening methods are primarily employed: toludine blue staining (visually detectedlesions: sensitivity 70-100%, specificity 25-67%), photodynamic diagnosis (sensitivity 94-99%, specificity 60-89%), autofluorescence (no data published so far) and modern oral cytology (sensitivity 80%,specificity 95-100%). Additional analytic procedures such automated image analysis, DNA image cytometry and immunocytochemistry can be used to enhance the low sensitivity of conventional oral cytology. While these methods have achieved sensitivity and specificity approaching 100%, the studies involved clearly-defined entities such as large oral squamous cell carcinomas and aphthae. The modern and methodenhanced oral cytology is a simple, value-based and inexpensive tool for early diagnosis of oral squamous cell carcinoma and its precursor lesions. Surgical biopsy and histopathological examination remains the gold standard for definitive diagnosis.

Gupta A, Singh M(2007) To evaluate the usefulness of toludine blue and brush biopsy in precancerous oral lesions and squamous cell carcinoma.The study was conducted at Moti Lal Nehru Medical College, Allahabad, India. Ninety-six patients with suspicious oral lesions who attended the outpatient clinics of otorhinolaryngology were screened with in vivo toludine blue staining and oral brush biopsy.Oral brush biopsy showed high specificity and sensitivity. Toludine blue staining was highly sensitive and moderately specific for malignant lesions but less sensitive for premalignant lesions.Early detection of oral carcinoma is possible even at the precancerous stages by using noninvasive, painless and outpatient procedures, such as in vivo toludine blue staining and brush biopsy.

Kerr AR Shah SS(2006) Department of oral and maxillofacial pathology USA. This article outlines how to perform a standard comprehensive extraoral and intraoral examination and the existing commercially available adjunctive techniques for the early detection of oral cancer and premalignant lesions. Visualization-based techniques (e.g., autofluorescence and chemiluminescence), toludine blue vital staining, cytopathologic tests and high-risk human papillomavirus testing are discussed in detail, including the indications and protocols for use, their advantages and disadvantages and clinical cases Recent advances in techniques for detecting oral premalignant lesions and oral squamous cell carcinoma have improved the chances of early diagnosis. Adjuncts for detection of lesions include toludine blue staining and cytologic examination. The primary objective of this study was to assess the efficacy of 1% toludine blue (modified Mashberg technique) and cytology in detection of oral premalignant lesions and oral squamous cell carcinoma

Silverman SJR(2005) had conducted a study on oral cancer screening using visualization techniques. These visual techniques can be divided into two general categories. One is the simple visual screening method, such as direct visual inspection, during which theoral mucosa is visualized with either the naked eye or a low powered magnification device after the application of a solution of 1% acetic acid that is used as a chemical contrast agent to highlight regions .The advantages of DVI compared with oral cytology for these settings are that it is inexpensive , it does not require a laboratory infrastructure, and it provides an immediate result.

Mashberg A , Samit (2005) An examination of the oral cavity and oropharynx in asymptomatic patients at high risk requires an orderly visual inspection of the entire oral and oropharyngeal mucosa with particular attention to the tongue, floor of mouth, soft palate, uvula, tonsillar pillars, and the lingual aspects of the retromolar trigones.

Completion and clear documentation of the entire examination should be recorded. Detected lesions that do not resolve in a reasonable length of time--two to three weeks--require intense and assiduous investigation. The following specifics should be considered. 1. Alcohol drinkers and cigarette smokers, especially those 40 years of age and older, are at very high risk for the development of upper aerodigestive tract and lung squamous carcinomas. 2. The floor of the mouth, the ventrolateral tongue, and the soft palate complex are the high-risk sites within the oralcavity and oropharynx. 3. Persistent mucosal erythroplasia rather than leukoplakia is the earliest visual sign of oral and oropharyngeal carcinoma. These lesions should not be regarded merely as precancerous changes. The evidence indicates that these lesions in high-risk sites should be considered to be invasive carcinoma or carcinoma in situ unless proven otherwise by biopsy. 4. Toludine blue staining is a useful diagnostic adjunct, particularly as a method of ruling out false-negative clinical impressions. It may also be used as a rinse in high-risk patients to encompass the entireoral mucosa after a negative clinical examination and as a guide to improve biopsy yields. 5. If oral or oropharyngeal cancer is identified, evaluations of the larynx, hypopharynx, esophagus, and lungs should be performed to rule out multiple primary cancers

Jahanshah salehinjad et.al., (2003) A total of 60 smokers and non-smokers with an age range of 30-40 , were selected for the study . These were patients of the Faculty of Dentistry of the Mashhad University of Medical sciences , for routine dental checkups .The smokers had been using a minimum of 20 cigarettes a day for atleast 10 years. Neither the smokers nor non-smokers had any oral lesions ,systemic disease or even any histopathological dysplasia in microscopic evaluation. The smears were taken from clinically normal buccal mucosa.

CONCEPTUAL FRAME WORK

The framework is a brief explanation of the theory or those portions of a theory that are to be tested in a quantitative study. Conceptual framework presents the logically constructed concepts of the research study. Conceptual framework is usually constructed by using the researcher's own experience.

The conceptual frame work of the study was derived from the Roy's Adaptation Theory" by Sr.Callista Roy. This theory is concerned with the focus, target and the nursing care indicated.

The investigator has concerned the focus as oral mucosa assessment, the target as the identification of premalignant changes and the indicated nursing care is the application of Toludine Blue test to identify the pre malignant changes.

The assessment of demographic variable of age, gender, education and occupation income in assessed and also the medical related variables like habit of tobacco chewing, alcohol consumption is also assessed. Selection of samples was based in the oral mucosal assessment scale.

In pre-assessment the inspection of oral mucosa with magnifying less in done.

In this system input, throughput and output is used.

INPUT:

Input is identified as stimuli that can come from the environment or from within the person and person's adaptation level. The intervention is toludine blue test. The investigatory intervened the indicated nursing actions

Step 1:

The first step is, rinsing of mouth with 1% acetic acid for 20 seconds followed by

Step 2:

Rinsing of mouth with 1% toludine blue for 30 seconds followed by

Step 3:

Rinsing of mouth with 1% acetic acid for 20 seconds

Throughput

Through put makes use of an individual's process and effectors. It denotes the post assessment as inspection of oral mucosa by magnifying lens after 5 minutes of toludine blue test.

Out put

Output refers to the subject oral mucosa changes. It denotes the pre malignant changes

In the output, the assessment of pre-malignant changes includes the following.

The pre-malignant changes are

- Normal
- Inflamed
- Leukoplakia
- Erythroplakia

The investigator identified that there were some pre-malignant changes among the tobacco chewers

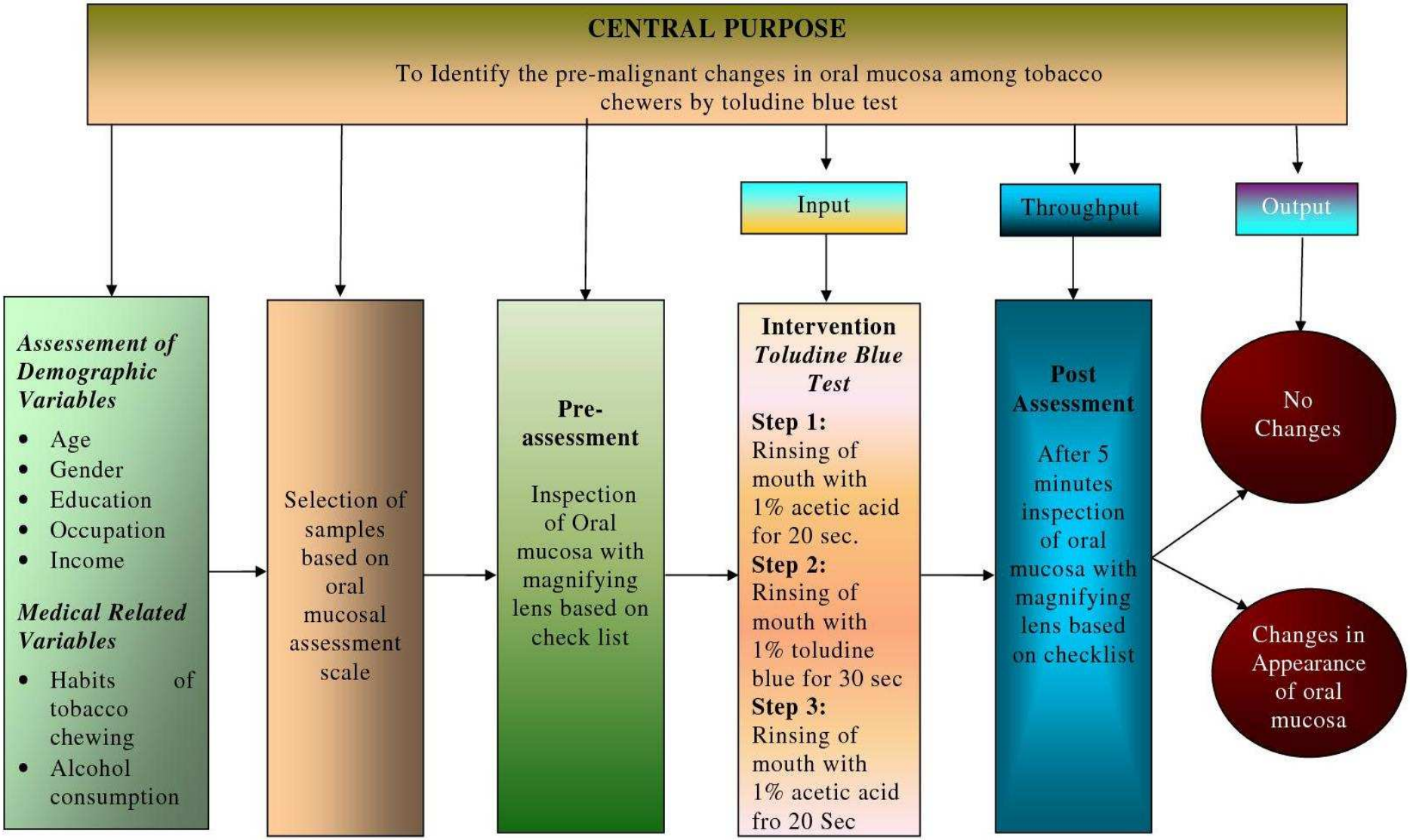

FIGURE 1: CONCEPTUAL FRAME WORK OF MODIFIED ROY'S ADAPTATION MODEL

CHAPTER- III

"Much of the research is a systematic attempt to exploit what is known and make it better."

-Kevin Kelly.

RESEARCH METHODOLOGY

The methodology of research indicates the general pattern of organizing the procedure for gathering valid and reliable data for the purpose of investigation. This chapter deals with steps used for collecting and organizing data. It includes research design, research approach, setting, sample and sampling technique, development and plan for data analysis.

The present study is designed to rule out the presence of pre malignant changes in oral mucosa among people admitted in Medical wards at Rajiv Gandhi Government General Hospital –Chennai-03.

In this study, research methodology adopted to identify the factors associated with the occurrence of pre malignant changes in oral mucosa among tobacco chewers male and female aged between 18-60 years admitted in medical wards at Rajiv Gandhi Government General Hospital –Chennai-03.

3.1 RESEARCH APPROACH

The research approach was selected in quantitative approach. The study was based on the observation and examination of the staining as a tool to assess the person for the early diagnosis and treatment.

3.2 RESEARCH DESIGN

The study was a non experimental design that provided factual information about the existing condition. Here the cross sectional

Descriptive design was used. This refers to the collection of data directly from the subject by structured questionarrie or interview.

3.3 VARIABLES IN THE STUDY

Independent Variable: Visual inspection of the oral mucosa by staining.

Dependent Variable: Premalignant /malignant changes of oral mucosa.

3.4 SETTING

This study was conducted in the medical wards at the Rajiv Gandhi Government General Hospital Chennai -03

3.5 POPULATION

The study population includes both male and female aged between 18 -60 years admitted in medical wards at Rajiv Gandhi Government General Hospital ,Chennai-3.

3.6 SAMPLE

All the subjects chewing tobacco admitted in Medical Wards with the age between 18 to 60 years.

3.7 SAMPLE SIZE

The sample size for the study was 60 which comprises of male and female admitted in medical wards.

3.8 SAMPLING TECHNIQUE

A non probability convenient sampling technique was used to select the subject. The subject consists of male and female aged between 18- 60 years ,who are admitted in medical wards.

3.9 CRITERIA FOR SAMPLE SELECTION

Inclusion Criteria

- Tobacco chewers with minimum having habit of tobacco chewing for less than 2 years.
- Males and females aged between 18-60 years.
- The subjects who are able to understand Tamil and English.

Exclusion Criteria

- The subjects who are not willing to participate in the study.
- Subjects who have cancer and other illness.
- Subjects with systemic diseases like diabetes, heart and neurological diseases .

3.10 DEVELOPMENT AND DESCRIPTION OF THE TOOL

The tool used in the study was an interview/observation of oral mucosa of tobacco chewers.

DESCRIPTION OF THE TOOL

The instrument used for the collection of data was a questionnaire for assessing the presence of risk factors of oral cancer. The questionnaire was prepared in English and data was collected through interview method. It has three sections –**SECTION A, B & SECTION C**

Section A: Demographic Data

Section B : Factors associated with the causes for pre malignant changes in the oral mucosa .

a) Tobacco chewing
b) Manner of tobacco usage
c) Tobacco usage per day

d) Smoking

e) Alcohol consumption

Section- C: Observation tool for Visual Inspection of the oral mucosa by magnifying lens.

1. Oral mucosal assessment
2. Appearance of oral mucosa
3. Visual inspection of oral mucosa after rinsing with 1% acetic acid , 1% toludine blue and again rinsing with 1% acetic acid with magnifying lens.
4. Presence of inflammation
5. Presence of leukoplakia
6. Presence of erythroplakia
7. Presence of fibrosis

3.11CONTENT VALIDITY

The content validity was obtained from the Director, Head of the Department, Institute of Internal Medicine, Rajiv Gandhi Government General Hospital and Medical Surgical Nursing Experts.

3.12 PILOT STUDY

A formal permission was obtained from The Director, Head of the Department ,Institute of Internal Medicine, Rajiv Gandhi Government General Hospital, Chennai-03. The pilot study was conducted in Medical Wards. 6 subjects selected by non probability convenient sampling technique. The results showed positive for pre malignant changes in oral mucosa by Toludine blue test. The study is practically feasible.

3.13 RELIABILITY

After pilot study reliability of the tool was assessed by using inter observer method and its correlation coefficient r value is 0.88. This correlation coefficient is very high and it is good tool to identify the pre malignant changes in oral mucosa by toludine blue test in medical wards.

3.14 DATA COLLECTION PROCEDURE

The investigator obtained formal written permission from Director, Institute of Internal Medicine, Rajiv Gandhi Government General Hospital Chennai -03 to conduct the study. The subjects were selected by non – probability convenient sampling technique, the investigator introduced herself explained the purpose of the study ensured confidentiality and informed written consents from the subjects. Interview techniques were obtained through information regarding demographic data. The study was done by the investigator after getting consent from subject based on the visualization of oral mucosa by magnifying lens. Total number of samples were 60 and average time is 40 minutes per subject. Initially the investigator inspect the subjects oral mucosa by magnifying lens with check list and intervention is rinsing of mouth with 1% acetic acid for 20 seconds followed by rinsing of mouth with 1% toludine blue for 30 sec followed by rinsing of mouth with !% acetic acid for 20 seconds. After 5 minutes post assessment was done by inspection of oral mucosa with magnifying lens based on check list. In post assessment the subjects were examined for pre-malignant changes in oral mucosa.

3.15 PLAN FOR DATA ANALYSIS:

Data analysis was planned to include descriptive and inferential statistics.

Descriptive statistics:

- ♣ Frequency and percentage distribution to analyse the demographic data for tobacco chewers
- ♣ Mean, Mean percentage and standard deviation to assess the scores.

Inferential statiststics:

- ♣ Chi-square to associate between the selected demographic variables.

3.16 ETHICAL CONSIDERATION

The proposal of the study was approved by the experts prior to the pilot study by the ethics committee. Each individual subject was informed about the purpose of the study informed consent was obtained, assurance was given to them that confidentiality and privacy would be maintained. The subject was informed that he or she was having the freedom of leaving the study.

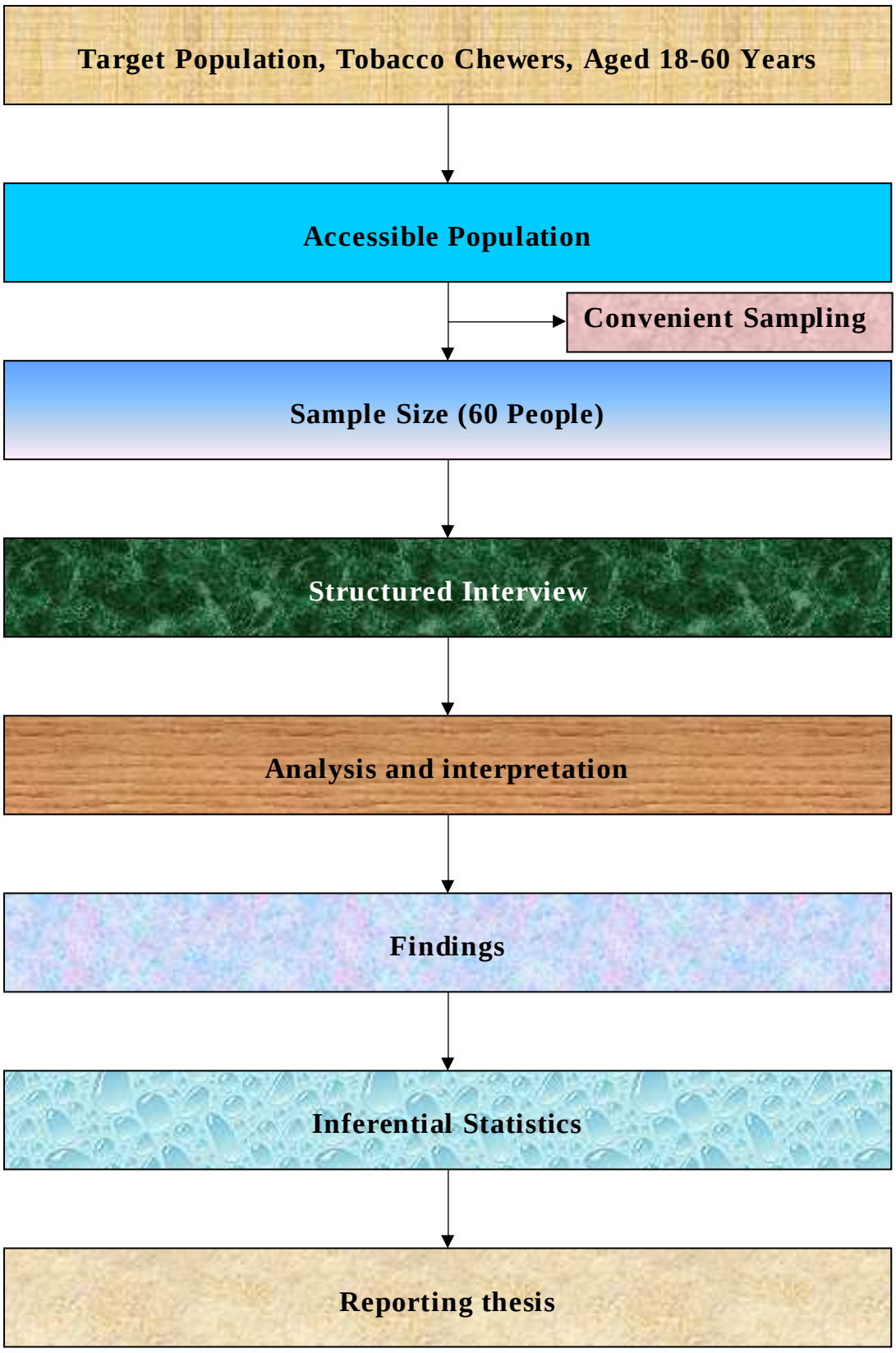

Figure-2 Schematic Representation of Research Methodology

CHAPTER – IV

"All great truths are simple in final analysis and easily understood; if they are not, they are not great truths".

- Napolean Hill

ANALYSIS AND INTERPRETATION OF THE DATA

This chapter explain the statistical analysis performed in the collected data. Analysis is a method for rending quantitative, meaningful and providing intelligible information, so that the research problem can be studied and tested the relationship between the variables.

Descriptive and inferential statistics were used for analyzing data in the light of the objectives of the study.

The data analysis has been explained under following sections

Section A: Demographic variables of samples.

Section B: Medical related variables

Section C: Pre and Post assessment of changes in oral mucosa before and after the application of Toludine Blue

Section D: Association of demographic variables with premalignant changes in oral mucosa

SECTION A

Table:1 Percentage Distribution Of Demographic Data (N=60)

Demographic variables		No. of tobacco Chewers	%
Age	20 -30 yrs	10	16.7%
	31 -40 yrs	14	23.3%
	41 -50 yrs	20	33.3%
	51 -60 yrs	16	26.7%
Sex	Male	35	58.3%
	Female	25	41.7%
Marital status	Married	50	83.3%
	Widower	10	16.7%
Religion	Hindu	49	81.7%
	Muslim	1	1.7%
	Christian	10	16.7%
Type of family	Nuclear family	33	55.0%
	Joint family	27	45.0%
Educational status	Illiterate	9	15.0%
	Elementary	33	55.0%
	Higher secondary	16	26.7%
	Graduate	2	3.3%
Occupation	Private	26	43.3%
	Pensioner	8	13.3%
	Unemployed	26	43.3%
Income	< Rs.1000	47	78.3%
	Rs.1000 -2000	6	10.0%
	Rs.2000 -5000	7	11.7%
Area of residence	Rural	31	51.7%
	Urban	29	48.3%
Dietary pattern	Vegetarian	12	20.0%
	Non vegetarian	3	5.0%
	Mixed	45	75.0%

Demographic variables		No. of tobacco Chewers	%
Familial history of cancer	Yes	7	11.7%
	No	53	88.3%
If yes specify the relationship	Father	4	57.1%
	Mother	1	14.3%
	Brother	2	28.6%
Previous knowledge regarding cancer	Yes No	43 17	67% 33
If yes, specify	Mass media	10	16.7%
	Friends	12	20.0%
	Relatives	15	25.0%
	Health personnel	23	38.3%

Table 1 shows the demographic information of tobacco chewers those who are participated in the study. It was seen that majority of the subjects are between 41-50 years of age and 58.3% are males and 81.7% are Hindus 83.3% are married and 55% are living in Nuclear family 33% are studied upto elementary education and 78.3% (47) their monthly income is less than Rs.1000/-

75% (45) of them are taking mixed diet and 20% (12) of them are vegetarian 11.7% of them are having the family history of cancer. 67% (40) of them are aware of oral cancer and 33% (20) of them are not aware of cancer. But only 5% (3) of them are aware of the cancer screening measures.

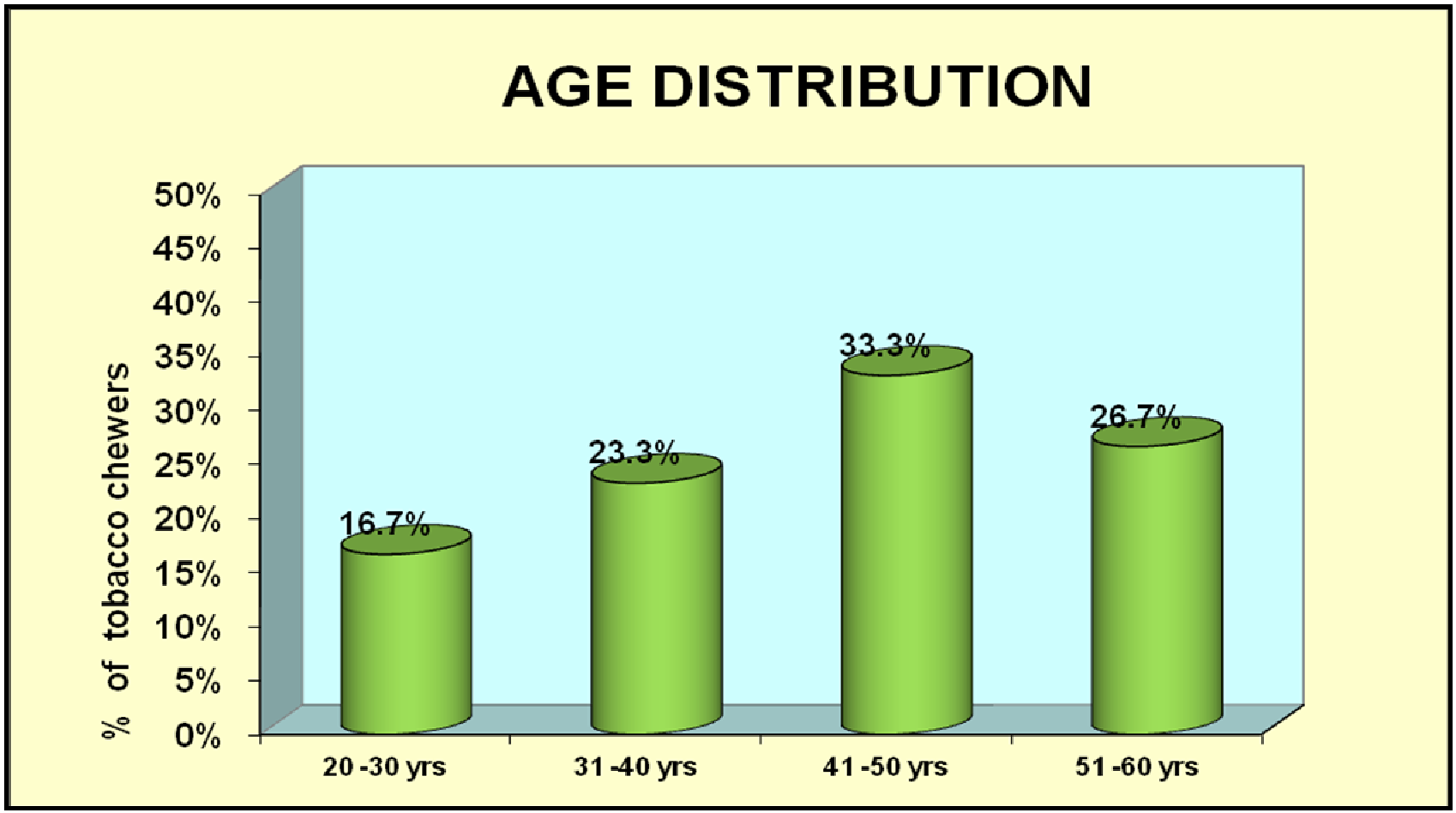

Figure 3: Distribution of Age in percentage

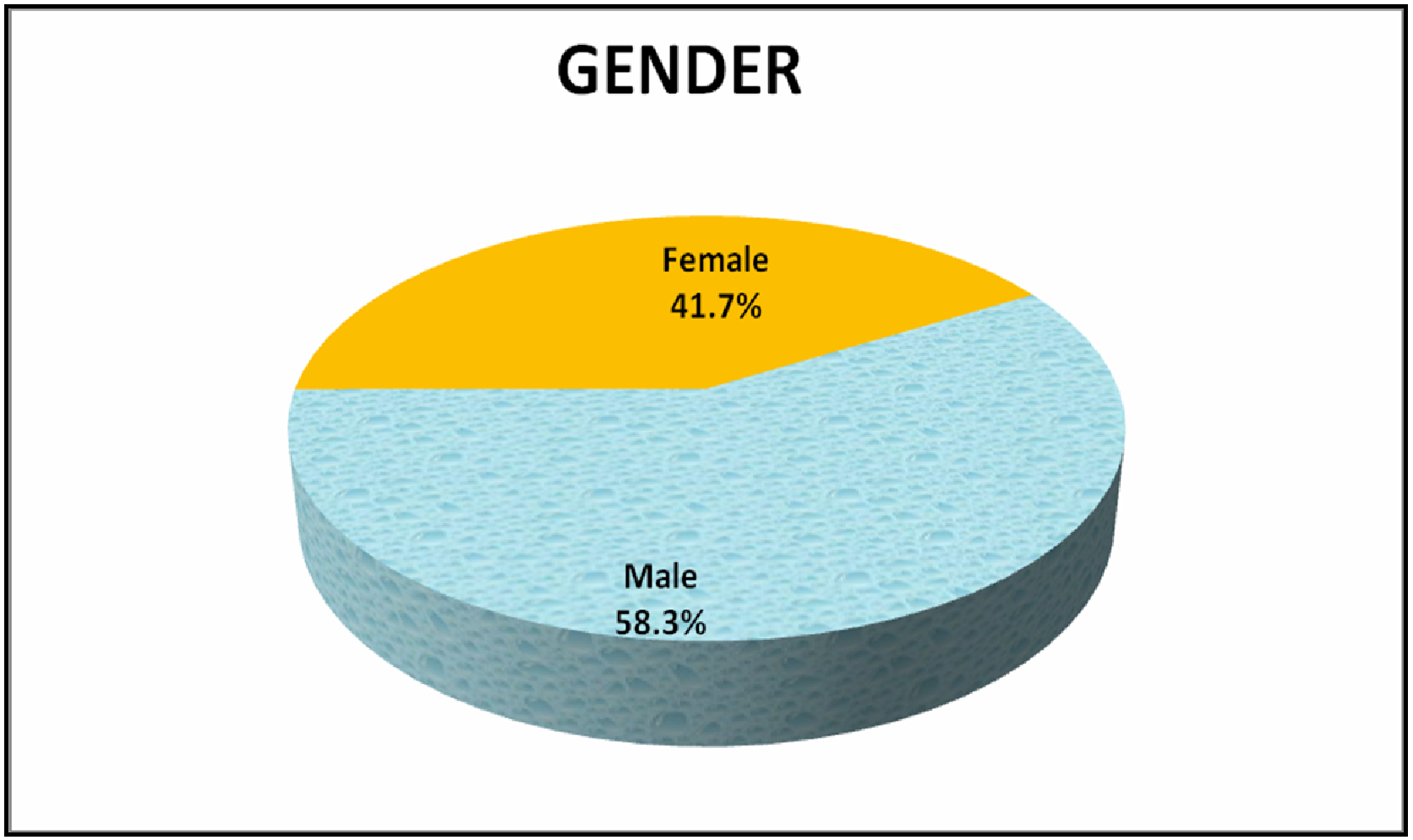

Figure 4: Distribution of Gender in percentage

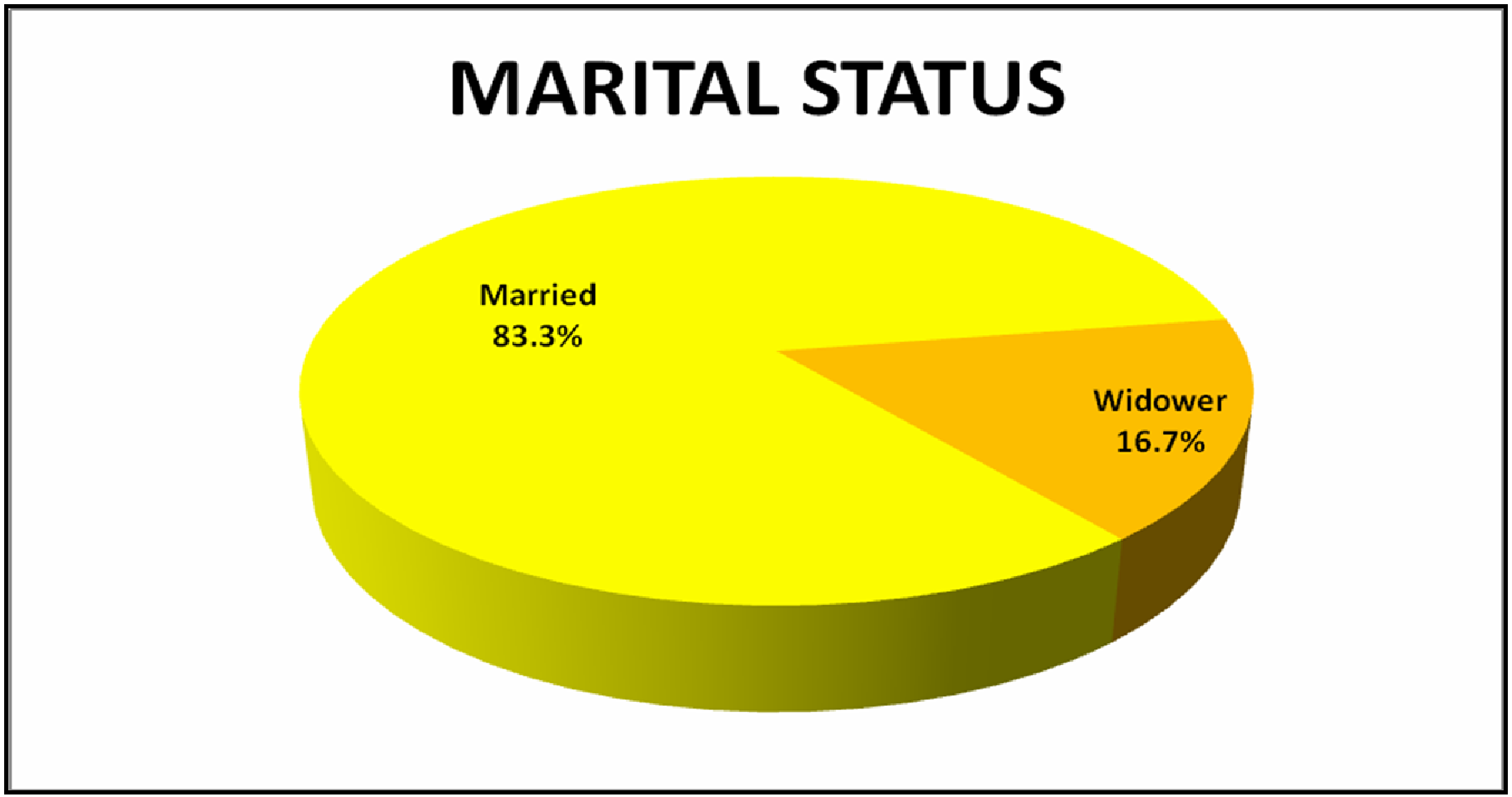

Figure 5: Distribution of Marital status in Percentage

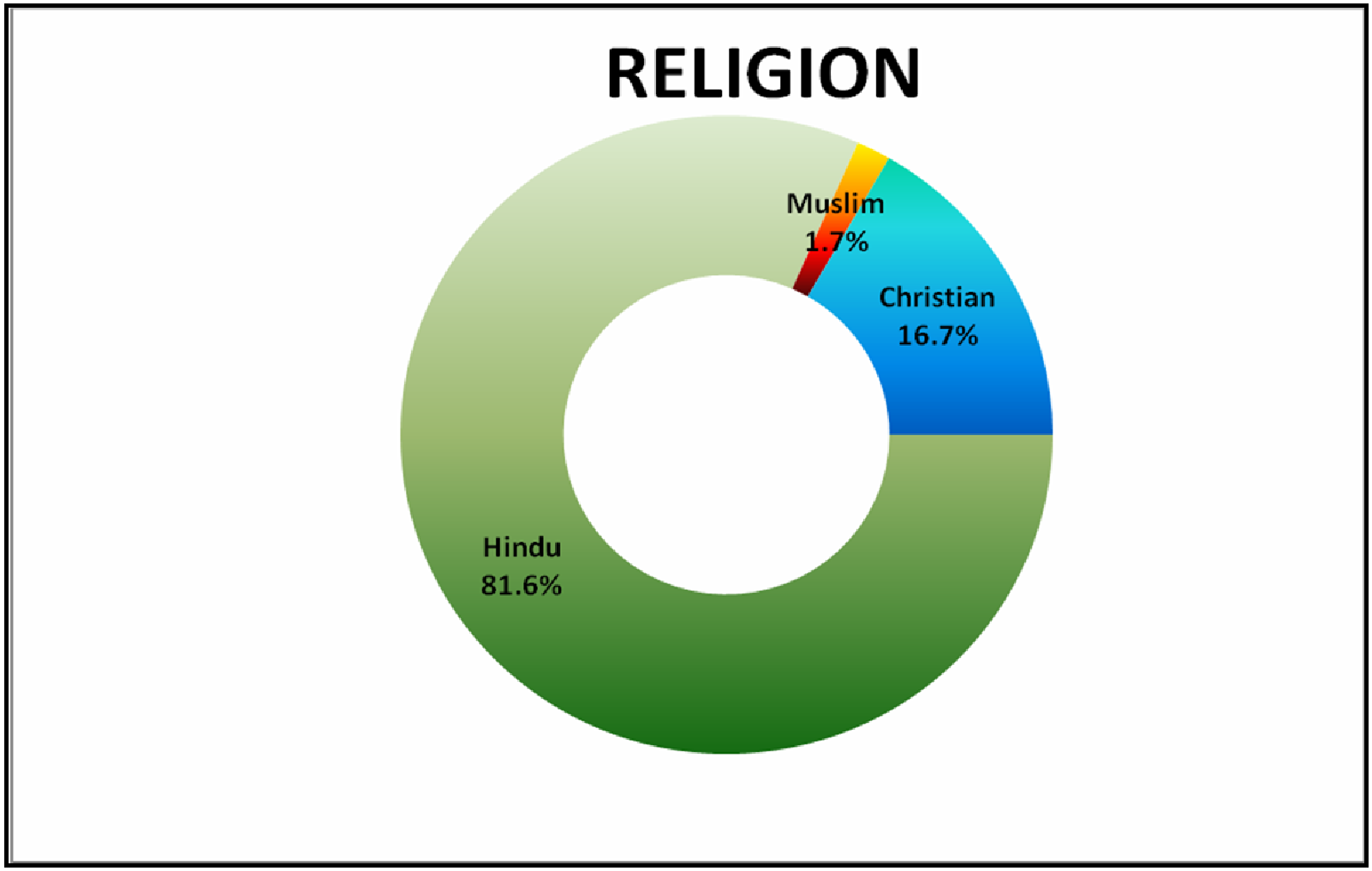

Figure 6: Distribution of Religion in percentage

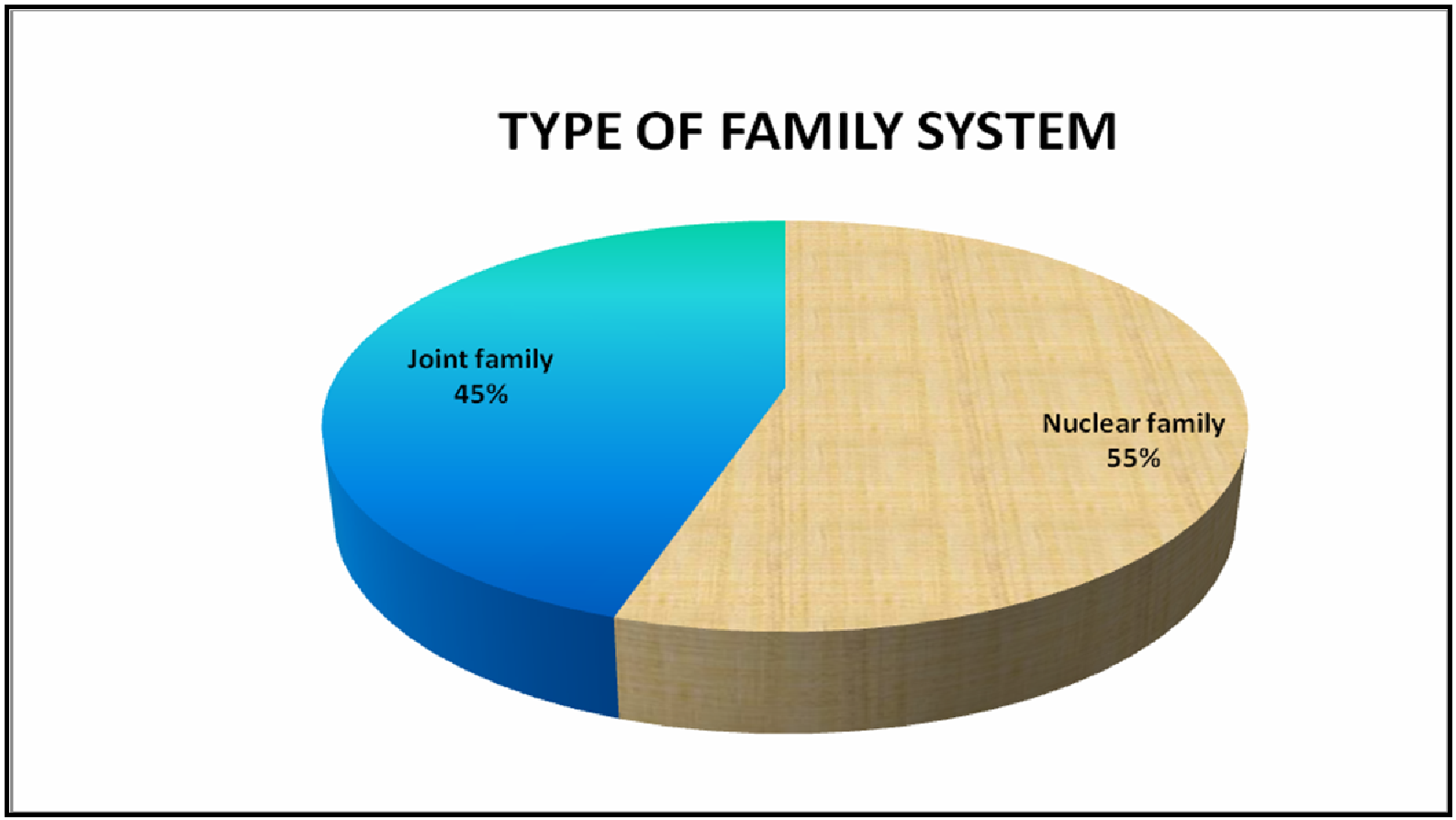

Figure 7: distribution of subjects according to type of family system

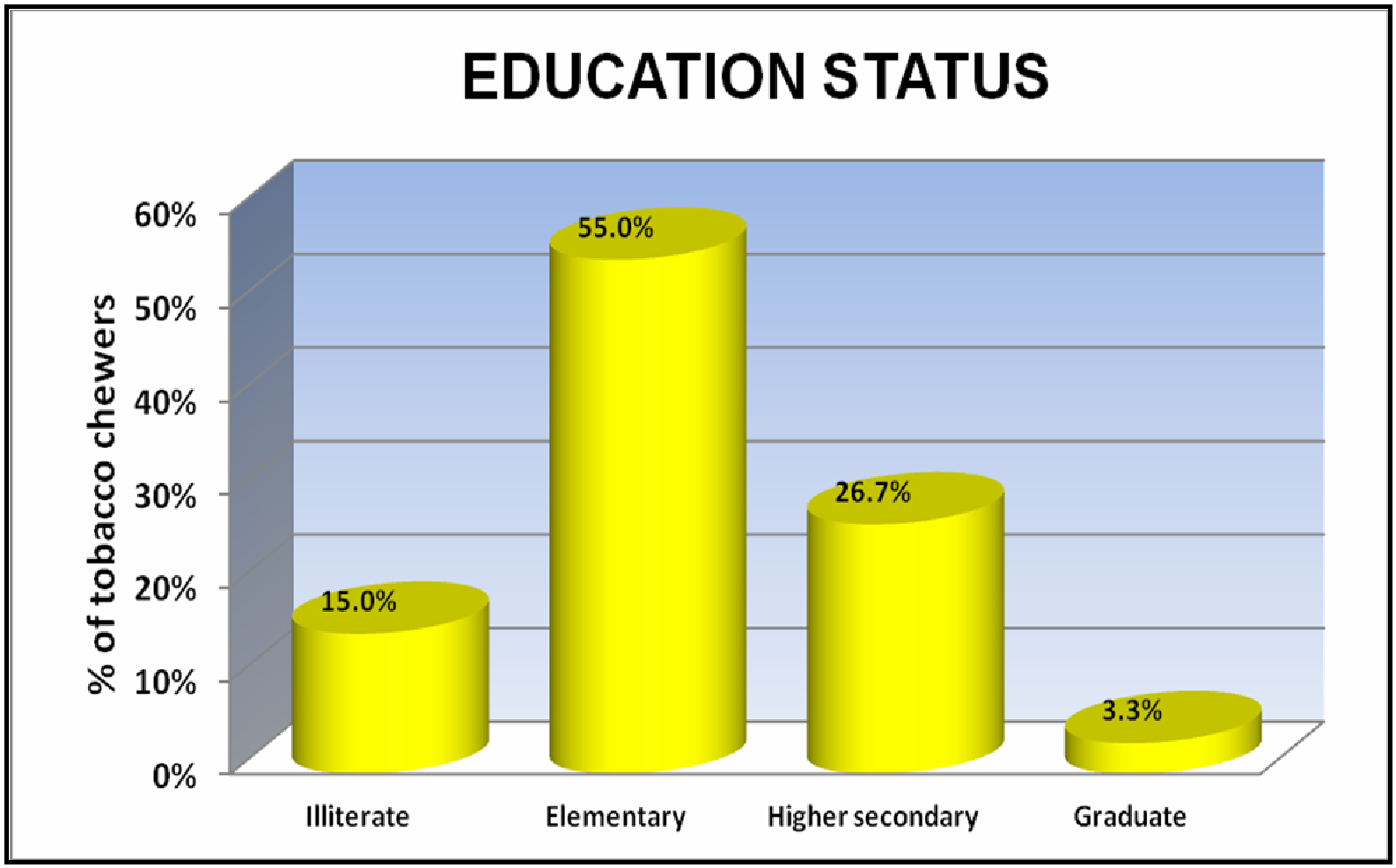

Figure 8: distribution of subjects according to Education status

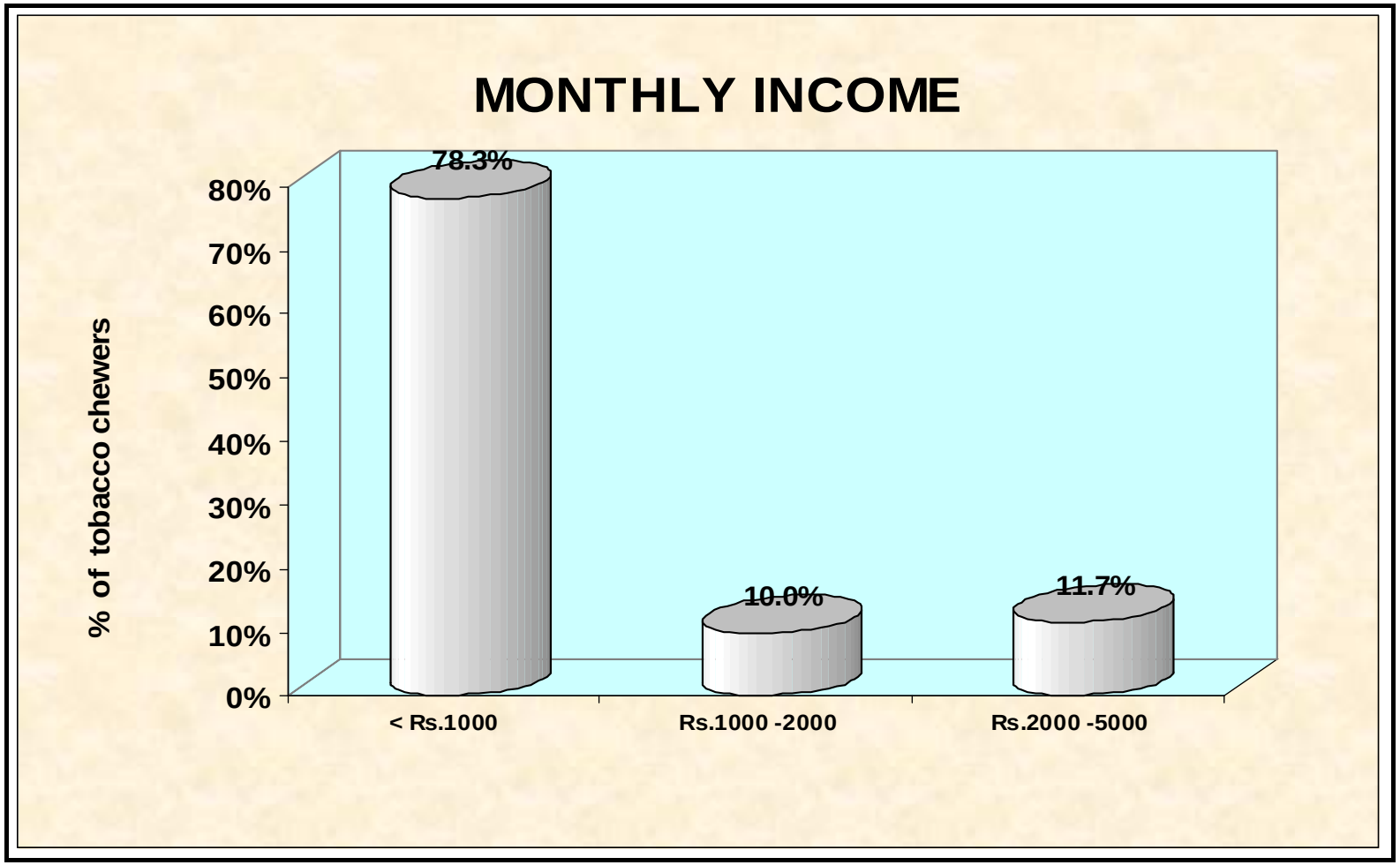

Figure 9 .Distribution of the subjects according to Monthly Income

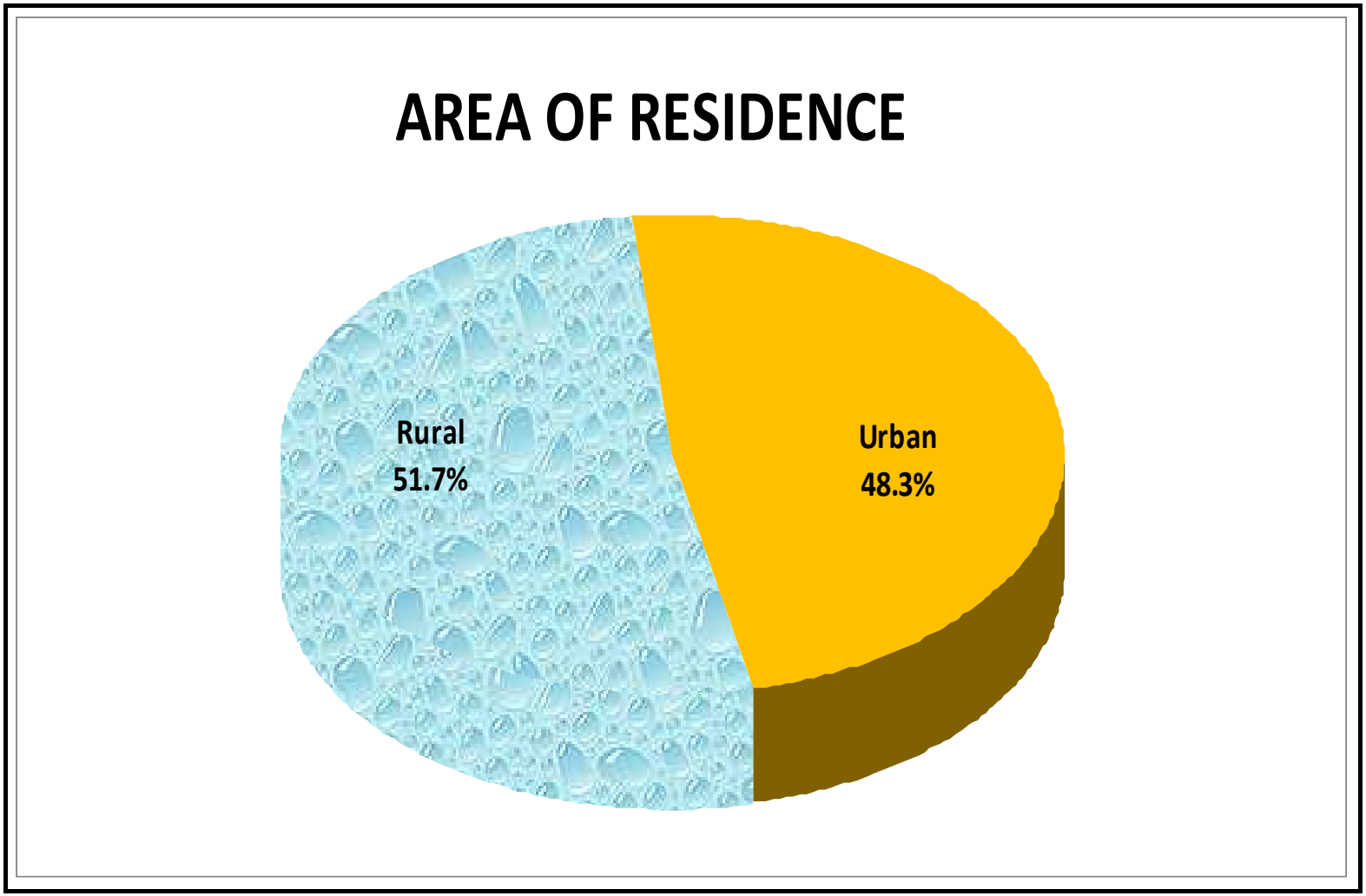

Figure 10 .Distribution of the subjects according to Area of residence

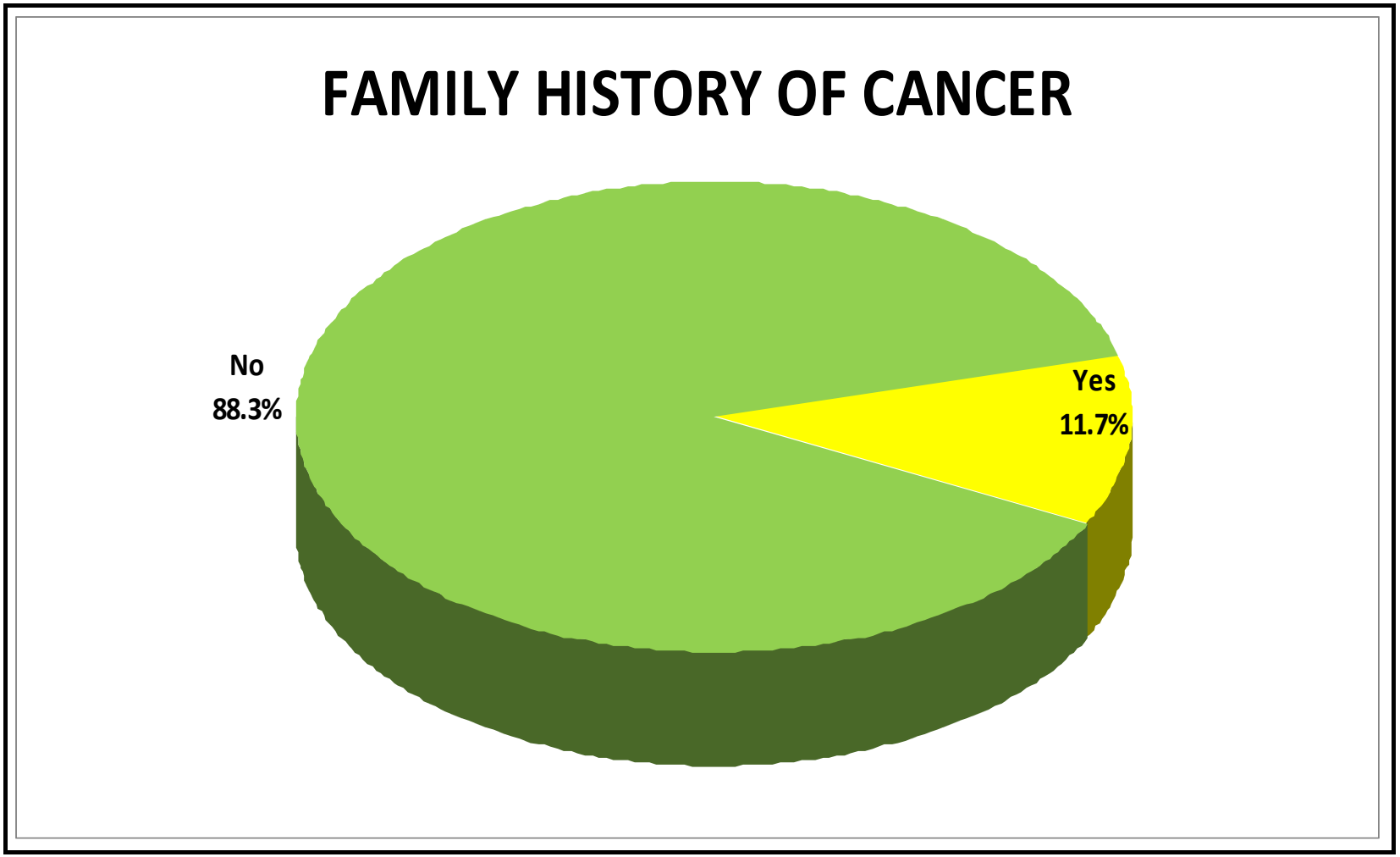

Figure 11 .Distribution of the subjects according to Family history of cancer

SECTION B

Table 2: Medical Related Information ***(N=60)***

		No. of tobacco chewers	%
Tobacco chewing	> 1 year	9	15.0%
	1-2 years	15	25.0%
	>2 years	36	60.0%
Manner of tobacco usage	Chewing	24	40.0%
	Pan-parag	25	41.7%
	Snuff	5	8.3%
	Kanja	6	10.0%
Tobacco usage per day	3 times	19	31.7%
	3 -5 times	21	35.0%
	> 5 times	20	33.3%
Smoking	Yes	33	55.0%
	No	27	45.0%
if yes,how many cigratte/beedi perday	4 -8 numbers	20	60.6%
	8 -10 numbers	13	39.4%
Alcohol Intake	Yes	28	46.7%
	No	32	53.3%

This table 2 depicts that nearly 60% (36) subjects were having habit of tobacco chewing for more than 2 years and 25% (15) subjects were having 1-2 years and 15% (9) were more than one year of having habit of tobacco chewing.

41.7% (25) subjects were using pan parag and 40% (24) subjects were chewing tobacco 35%(21) were using the tobacco for 3-5 times per day and 33.3% (20) were using more than 5 times per day.

Associated factors like smoking is 55% (33) subjects were smoking and 60.6% (20) subjects were smoking 4-8 cigarretes per day. 46.7% (28) subjects having the habit of taking alcohol along with tobacco chewing.

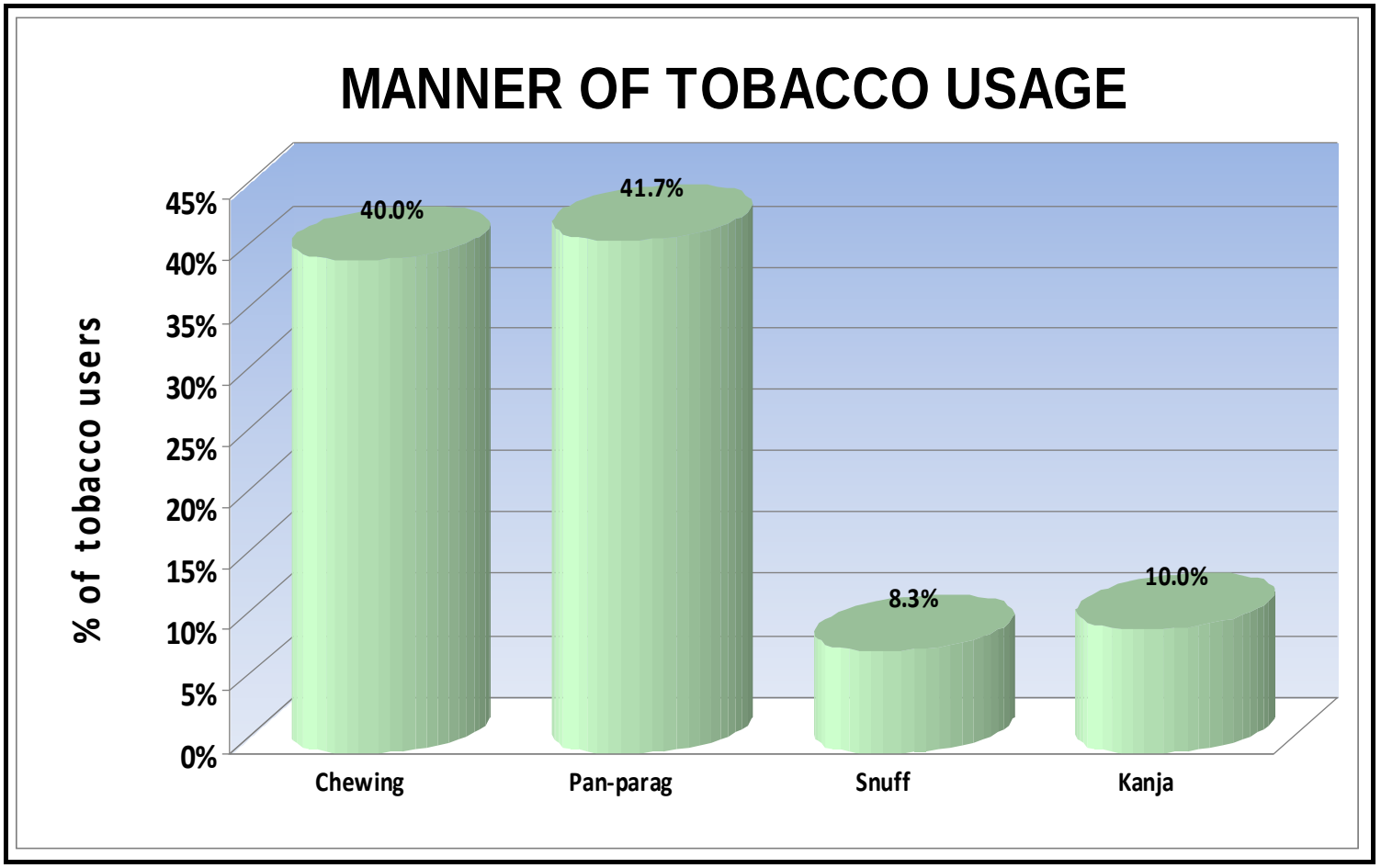

Figure 12 .Distribution of the subjects according to manner of tobacco use

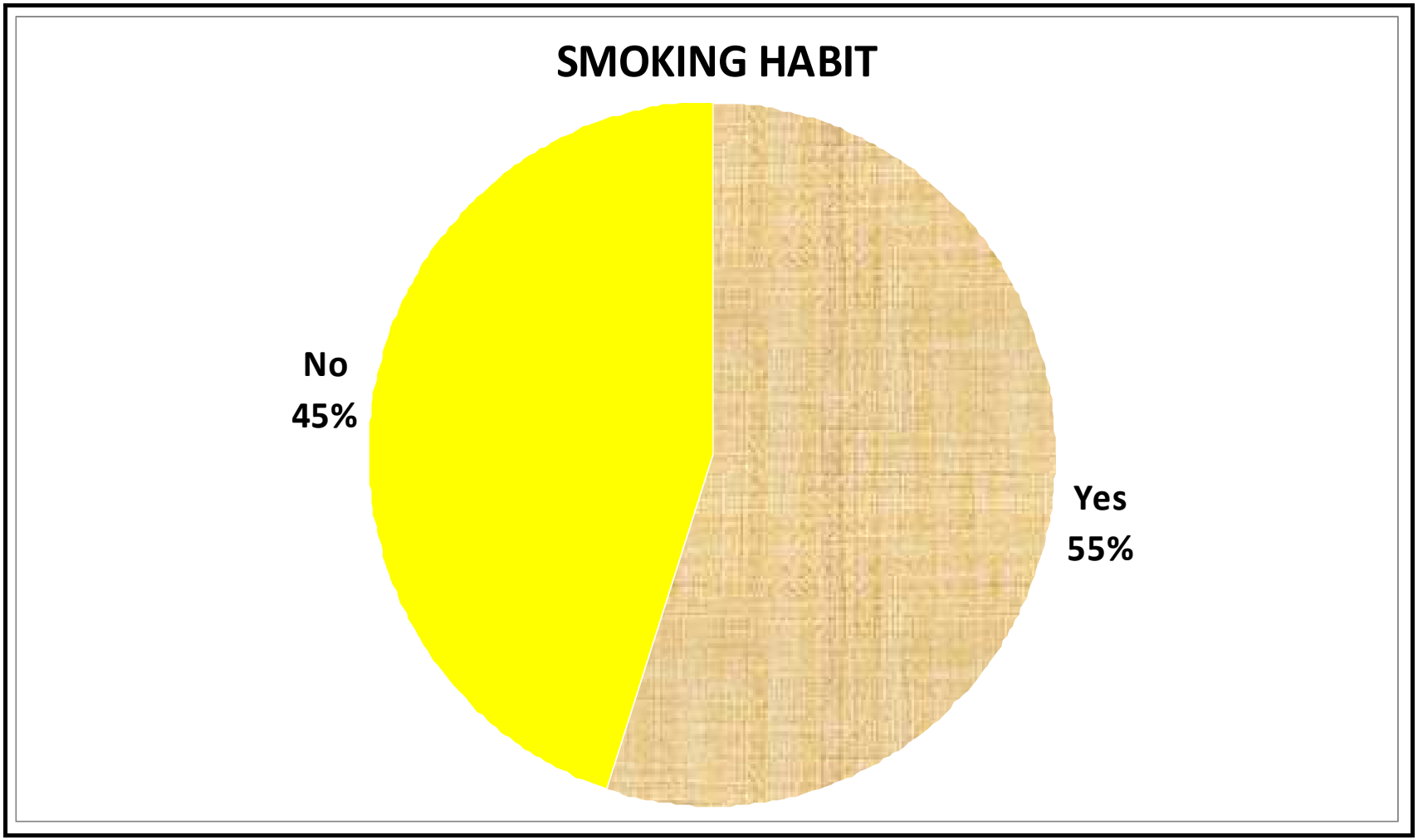

Figure 13 .Distribution of the subjects according to Smoking habit

Figure 14 .Distribution of the subjects according to Alcohol habit

Table 3: Observation tool for oral mucosal assessment

	No. of tobacco chewer	**%**
Normal	100	100.0%
Inflammed	0	0.0%
Leukoplakia	0	0.0%
Erythroplakia	0	0.0%
Fibrosis	0	0.0%

This table 3 describes about the appearance of oral mucosa. 100% of subjects were having normal mucosa while examining the oral mucosa.

Table 4: Assessment of Oral mucosa after application of toludine blue among tobacco chewers.

	No. of tobacco chewer	**%**
Normal	30	50.0%
Inflammed	10	16.7%
Leukoplakia	13	21.7%
Erythroplakia	7	11.7%
Fibrosis	0	0.0%
Total	60	100.0%

Table 4 shows the assessment of premalignant changes in oral mucosa after the application of toludine blue among tobacco chewers. 50% of the tobacco chewers were having normal oral mucosa 16.7% of the tobacco chewers were having inflamed oral mucosa. 21.7% of them were having leukoplakia and 11.7% of them were having Erythroplakia.

Table 5: Comparison of the effectiveness of changes in oral mucosa before and after the application of toludine blue among tobacco chewers.

	Pre assessment		Post assessment		Chi square test
	No. of tobacco chewer	**%**	**No. of tobacco chewer**	**%**	
Normal	100	100.0%	30	50.0%	$\chi 2=61.54$
Inflammed	0	0.0%	10	16.7%	P=0.001***
Leukoplakia	0	0.0%	13	21.7%	DF=3
Erythroplakia	0	0.0%	7	11.7%	
Fibrosis	0	0.0%	0	0.0%	
Total	100	100.0%	60	100.0%	

Table 5 depicts that before application of toludine blue, all the tobacco chewer were having normal oral mucosa. After application of toludine blue, only 50% are normal, 16.7% inflamed, 1.7% leukaplakia and 11.7% erythroplakia changes.

This difference is statistically significant and it was calculated using chi square test.

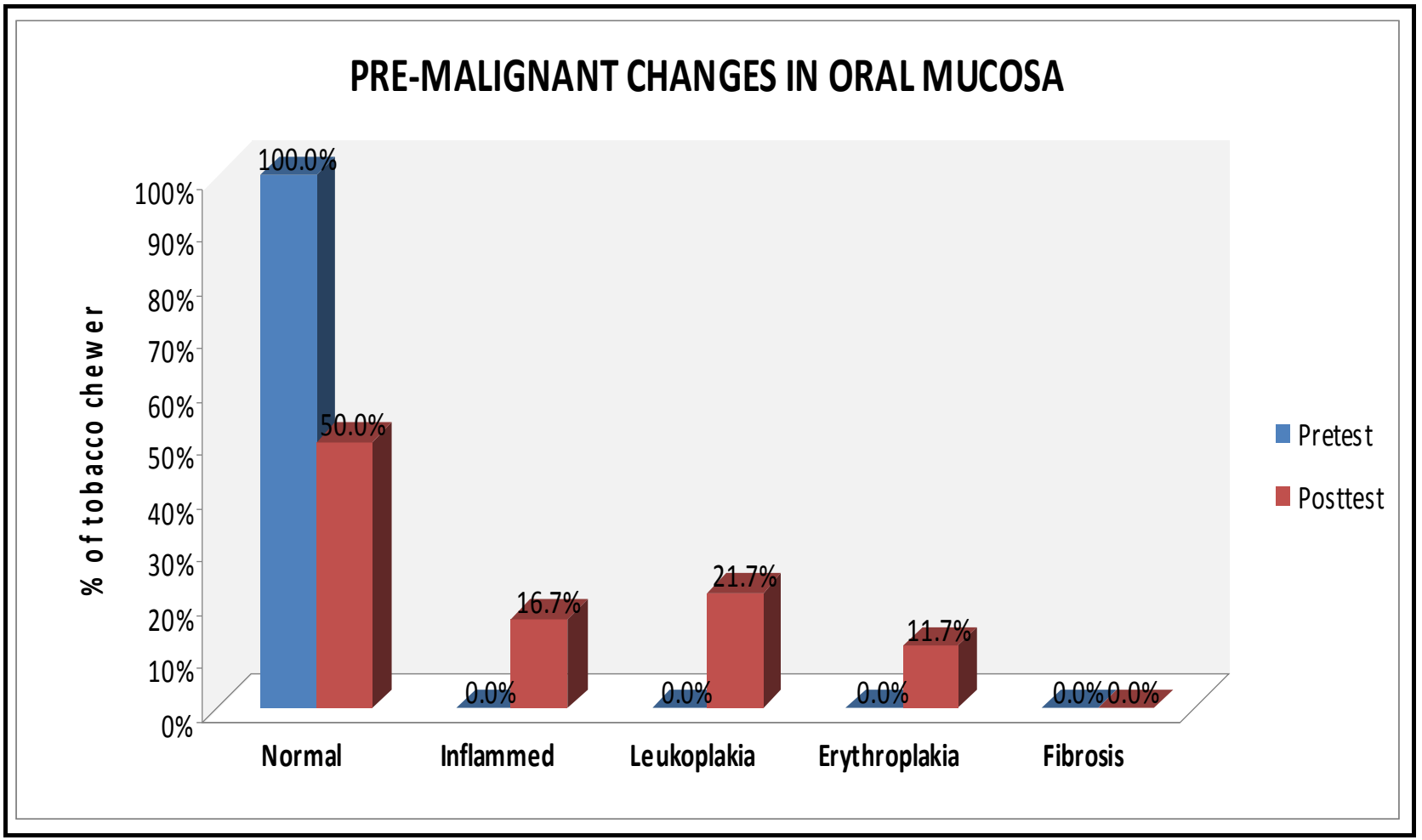

Figure 15 .Distribution of the subjects according to pre-malignant changes in oral mucosa

Table 6: Difference between before and after assessment of premalignant changes in oral mucosa among tobacco chwers.

	Normal	**Oral mucosa changes**	**Percentage Difference with 95% Confidence interval**
Pre-Assessment	100%	0.0%	50.0%(35.6% –64.3%)
Post-Assessment	50%	50%	

Table no 6 shows the difference between before and after assessment of pre malignant changes in oral mucosa among tobacco chewers.

Toludine Blue Test identifies 50% of the cases(30 out of 60) tobacco chewers were having changes in oral mucosa.

Differences between pretest and posttest score was analysed using proportion with 95% Confidence Interval .

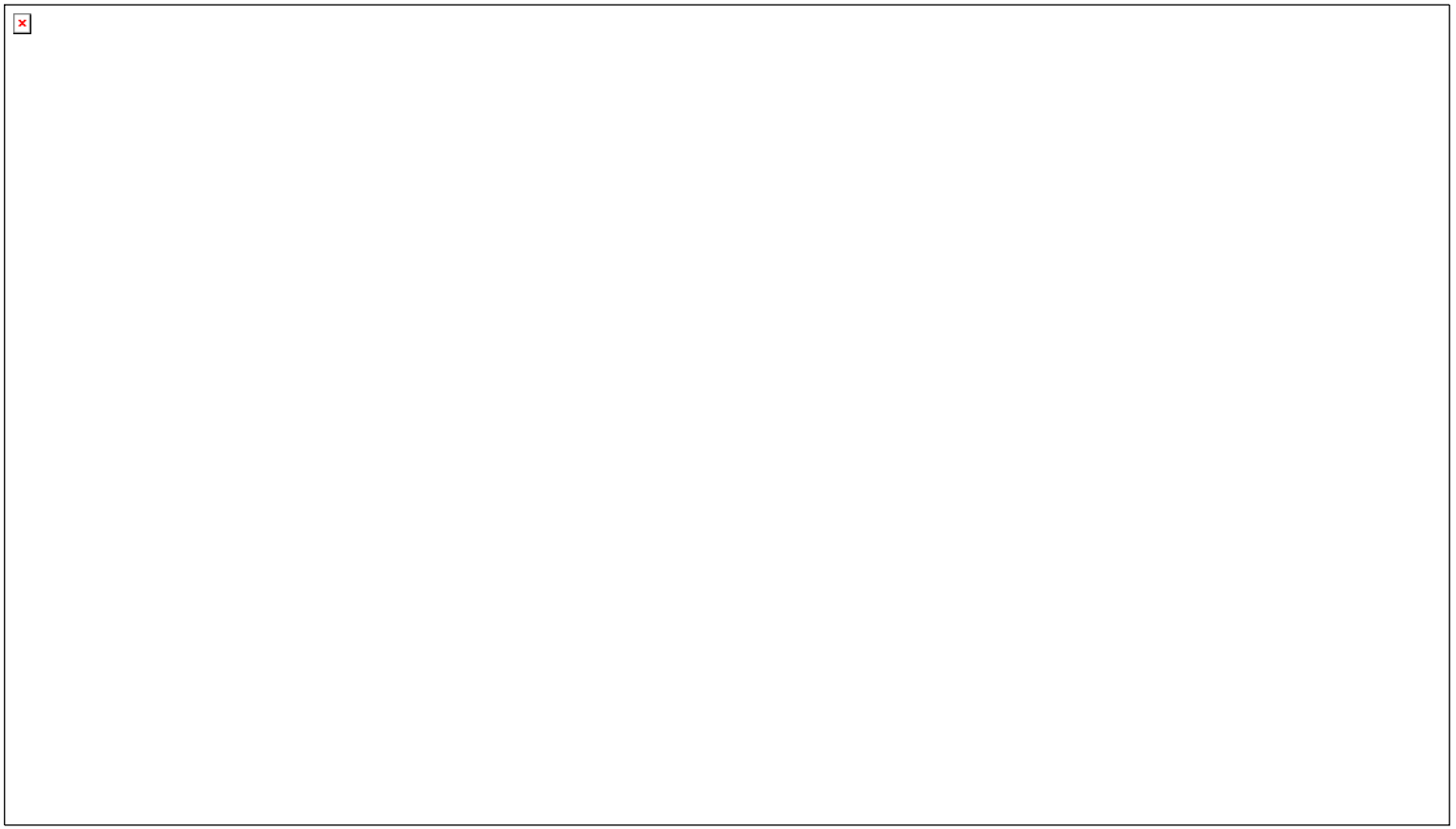

Figure 16 .Distribution of the subjects according to pre-assessment and post-assessment changes

Table 7: Association Between Demographic Variables And Pre-Malignant Changes in Oral Mucosa

		TOLUDINE BLUE TEST ASSESSMENT								Total	Chi square test
		Normal		Inflammed		Leukoplakia		Erythroplakia			
		n	%	n	%	n	%	n	%		
Age	20 -30 yrs	8	80.0%	1	10.0%	1	10.0%	0	0.0%	10	χ^2=17.22 P=0.04*
	31 -40 yrs	9	64.2%	3	21.4%	2	14.3%	0	0.0%	14	
	41 -50 yrs	9	45.0%	5	25.0%	3	15.0%	3	15.0%	20	
	51 -60 yrs	4	25.0%	1	6.2%	7	43.7%	4	25.0%	16	
Sex	Male	19	54.3%	2	5.7%	7	20.0%	7	20.0%	35	χ^2=11.46 P=0.01**
	Female	11	44.0%	8	32.0%	6	24.0%	0	0.0%	25	
Marital status	Married	26	52.0%	9	18.0%	10	20.0%	5	10.0%	50	χ^2=1.65 P=0.64
	Widower	4	40.0%	1	10.0%	3	30.0%	2	20.0%	10	
Religion	Hindu	26	53.1%	6	12.2%	11	22.4%	6	12.2%	49	χ^2=8.42 P=0.20
	Muslim					1	100.0%			1	
	Christian	4	40.0%	4	40.0%	1	10.0%	1	10.0%	10	
Type of family	Nuclear family	15	45.5%	6	18.2%	7	21.2%	5	15.2%	33	χ^2=1.17 P=0.75
	Joint family	15	55.6%	4	14.8%	6	22.2%	2	7.4%	27	
Educational status	Illiterate	5	55.6%	2	22.2%	2	22.2%			9	χ^2=7.47 P=0.58
	Elementary	17	51.5%	3	9.1%	8	24.2%	5	15.2%	33	
	Higher secondary	8	50.0%	4	25.0%	2	12.5%	2	12.5%	16	
	Graduate			1	50.0%	1	50.0%			2	
Occupation	Private	13	50.0%	4	15.4%	4	15.4%	5	19.2%	26	χ^2=4.19 P=0.65
	Pensioner	4	50.0%	1	12.5%	3	37.5%			8	
	Unemployed	13	50.0%	5	19.2%	6	23.1%	2	7.7%	26	

		TOLUDINE BLUE TEST ASSESSMENT								Total	Chi square test
		Normal		Inflammed		Leukoplakia		Erythroplakia			
		n	%	n	%	n	%	n	%		
Income	< Rs.1000	22	46.8%	9	19.1%	11	23.4%	5	10.6%	47	χ^2=6.87P=0.33
	Rs.1000 - 2000	3	50.0%	1	16.7%	0	0.0%	2	33.3%	6	
	Rs.2000 - 5000	5	71.4%	0	0.0%	2	28.6%	0	0.0%	7	
Area of residence	Rural	15	48.4%	4	12.9%	9	29.0%	3	9.7%	31	χ^2=2.40 P=0.49
	Urban	15	51.7%	6	20.7%	4	13.8%	4	13.8%	29	
Dietary pattern	Vegetarian	4	33.3%	3	25.0%	4	33.3%	1	8.3%	12	χ^2=3.75 P=0.70
	Non vegetarian	2	66.7%	0	0.0%	1	33.3%	0	0.0%	3	
	Mixed	24	53.3%	7	15.6%	8	17.8%	6	13.3%	45	

* significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001

Table 7 shows the association between the pre- malignant lesion and their demographic variables had less education and less income, elders and males were having more changes than others. statistical significance was calculated using chi square test.

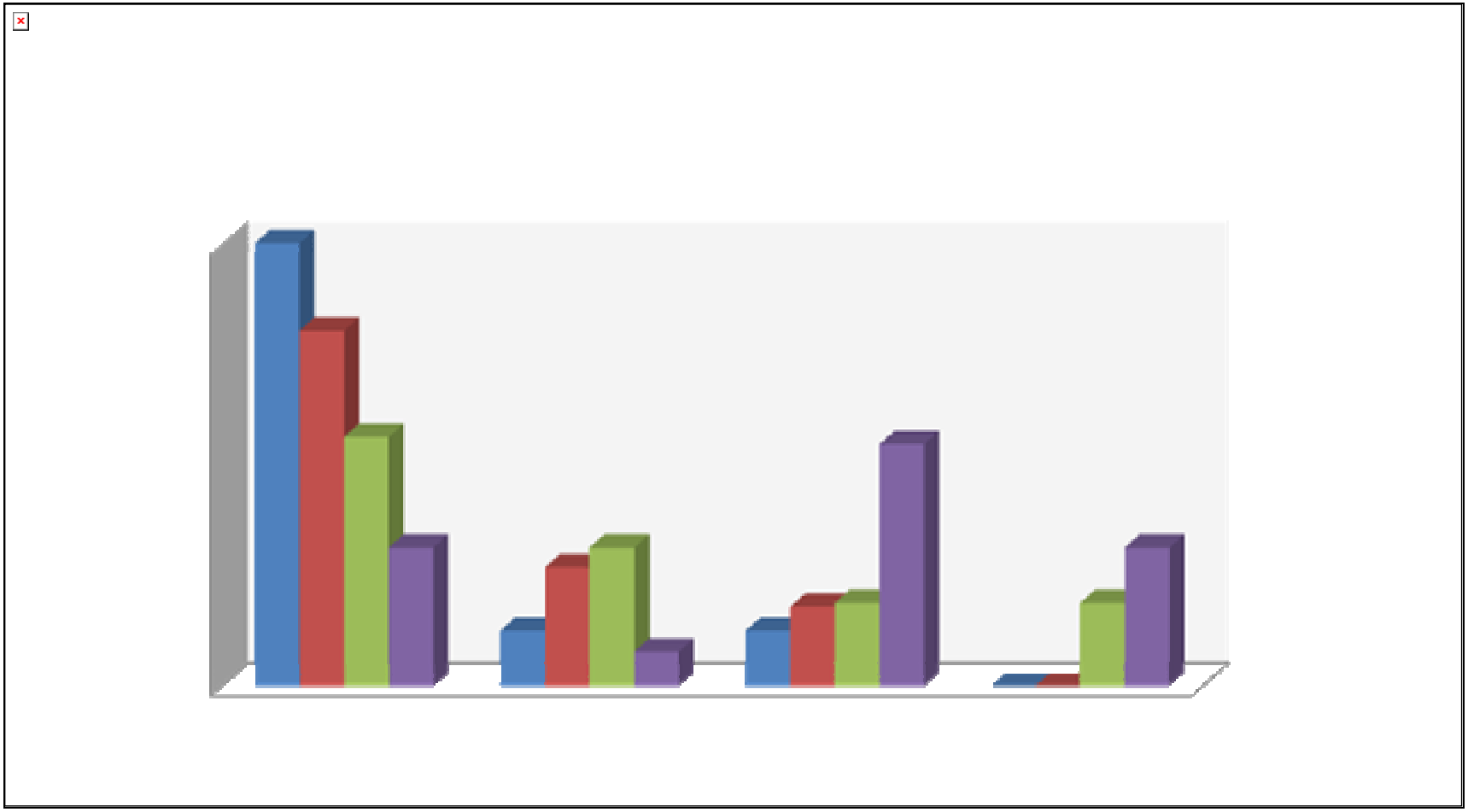

Figure 17: shows Association between Age and Pre-Malignant changes

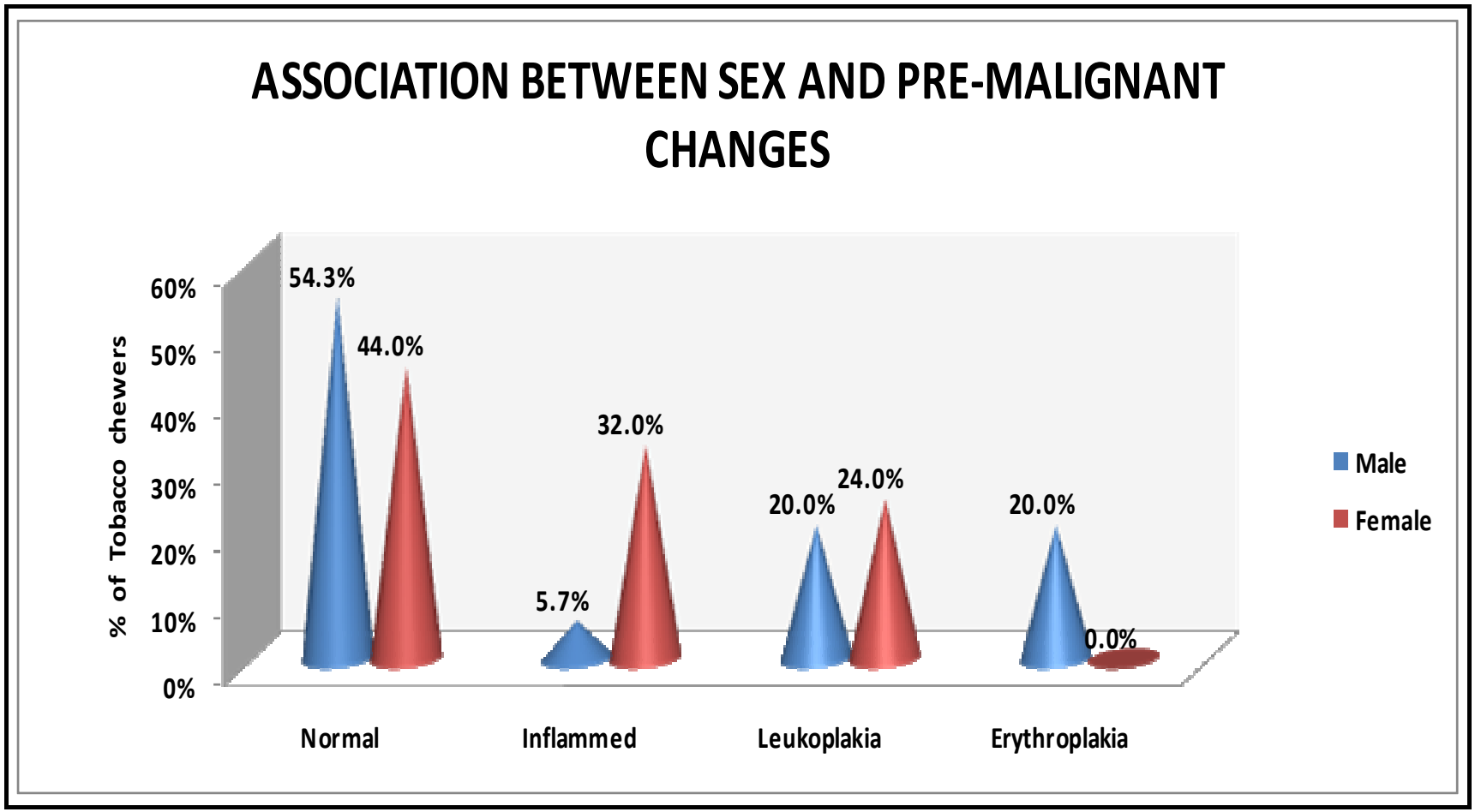

Figure 18: shows Association Between Sex And Pre- Malignant Changes

Table 8: Association between cancer related variables and malignant changes in oral mucosa

		TOLUDINE BLUE TEST ASSESSMENT								Total	Chi square test
		Normal		Inflammed		Leukoplakia		Erythroplakia			
		n	%	n	%	n	%	n	%		
Familial history of cancer	Yes	5	71.4%	0	0.0%	2	28.6%	0	0.0%	7	χ^2=3.14 P=0.36
	No	25	47.2%	10	18.9%	11	20.8%	7	13.2%	53	
If yes specify the relationship	Father	2	50.0%	0	0.0%	2	50.0%	0	0.0%	4	χ^2=2.10 P=0.35
	Mother	1	100.0%	0	0.0%	0	0.0%	0	0.0%	1	
	Brother	2	100.0%	0	0.0%	0	0.0%	0	0.0%	2	
Previous knowledge regarding cancer	Yes	30	50.0%	10	16.7%	13	21.7%	7	11.7%	60	χ^2=0.00 P=1.00
If yes, specify	Mass media	7	70.0%	2	20.0%	0	0.0%	1	10.0%	10	χ^2=7.02 P=0.15
	Friends	6	50.0%	1	8.3%	4	33.3%	1	8.3%	12	
	Relatives	10	66.7%			5	33.3%	0	0.0%	15	
	Health care personnel	7	30.4%	7	30.4%	4	17.4%	5	21.7%	23	

Table 8 shows the association between cancer related variables and pre-malignant changes in oral mucosa. None of the variables are associated. Statistical significance was calculated using chi square test.

Table 9: Association Between Tobacco Related Variables And Pre-Malignant Changes in Oral Mucosa

		TOLUDINE BLUE TEST ASSESSMENT								Total	Chi square test
		Normal		Inflammed		Leukoplakia		Erythroplakia			
		n	%	n	%	n	%	n	%		
Tobacco chewing	< 1 year	0	0.0%	0	0.0%	3	33.3%	6	66.7%	9	χ^2=8.31 P=0.14
	1-2 years	14	93.3%	0	0.0%	0	0.0%	1	6.7%	15	
	>2 years	16	44.4%	10	27.8%	10	27.8%	0	0.0%	36	
Manner of tobacco usage	Chewing	14	58.3%	0	0.0%	3	12.5%	7	29.2%	24	χ^2=52.90 P=0.001***
	Pan	13	52.0%	2	8.0%	10	40.0%	0	0.0%	25	
	Snuff	3	60.0%	2	40.0%	0	0.0%	0	0.0%	5	
	Kanja	0	0.0%	6	100.0%	0	0.0%	0	0.0%	6	
Tobacco usage per day	3 times	11	57.9%	0	0.0%	8	42.1%	0	0.0%	19	χ^2=40.16 P=0.001***
	3 -5 times	5	23.8%	10	47.6%	5	23.8%	1	4.8%	21	
	> 5 times	14	70.0%	0	0.0%	0	0.0%	6	30.0%	20	
Smoking	Yes	10	30.3%	7	21.2%	12	36.3%	4	12.1%	33	χ^2=13.9 P=0.03*
	No	20	74.1%	3	11.1%	1	3.7%	3	11.1%	27	
if yes,how many cigratte/beedi perday	4 -8 numbers	6	30.0%	8	40.0%	6	30.0%	0	0.0%	20	χ^2=4.82 P=0.18
	8 -10 numbers	4	30.8%	2	15.4%	5	38.5%	2	15.4%	13	
Alcohol Intake	Yes	18	64.3%	0	0.0%	3	10.7%	7	25.0%	28	χ^2=21.79 P=0.001***
	No	12	37.5%	10	31.3%	10	31.3%	0	0.0%	32	

* significant at P≤0.05 ** highly significant at P≤0.01 *** very high significant at P≤0.001

Table 9 shows the association between Tobacco related variables and pre-malignant changes in oral mucosa. Chewers, more time tobacco chewers, smokers and alcoholic persons were having more changes than others. Statistical significance was calculated using chi square test.

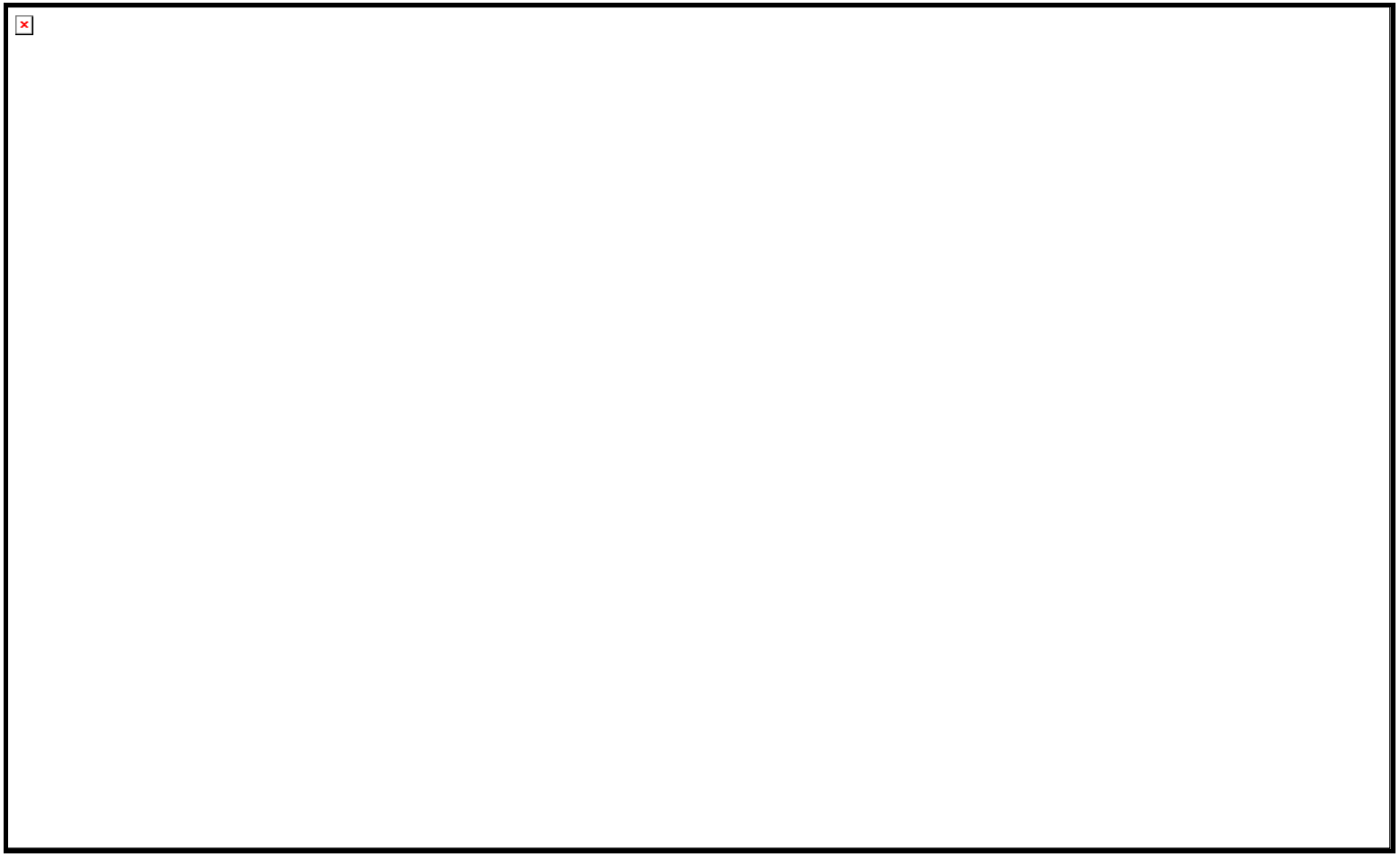

Figure 19: shows Association between Manner of Tobacco usage and pre- malignant changes

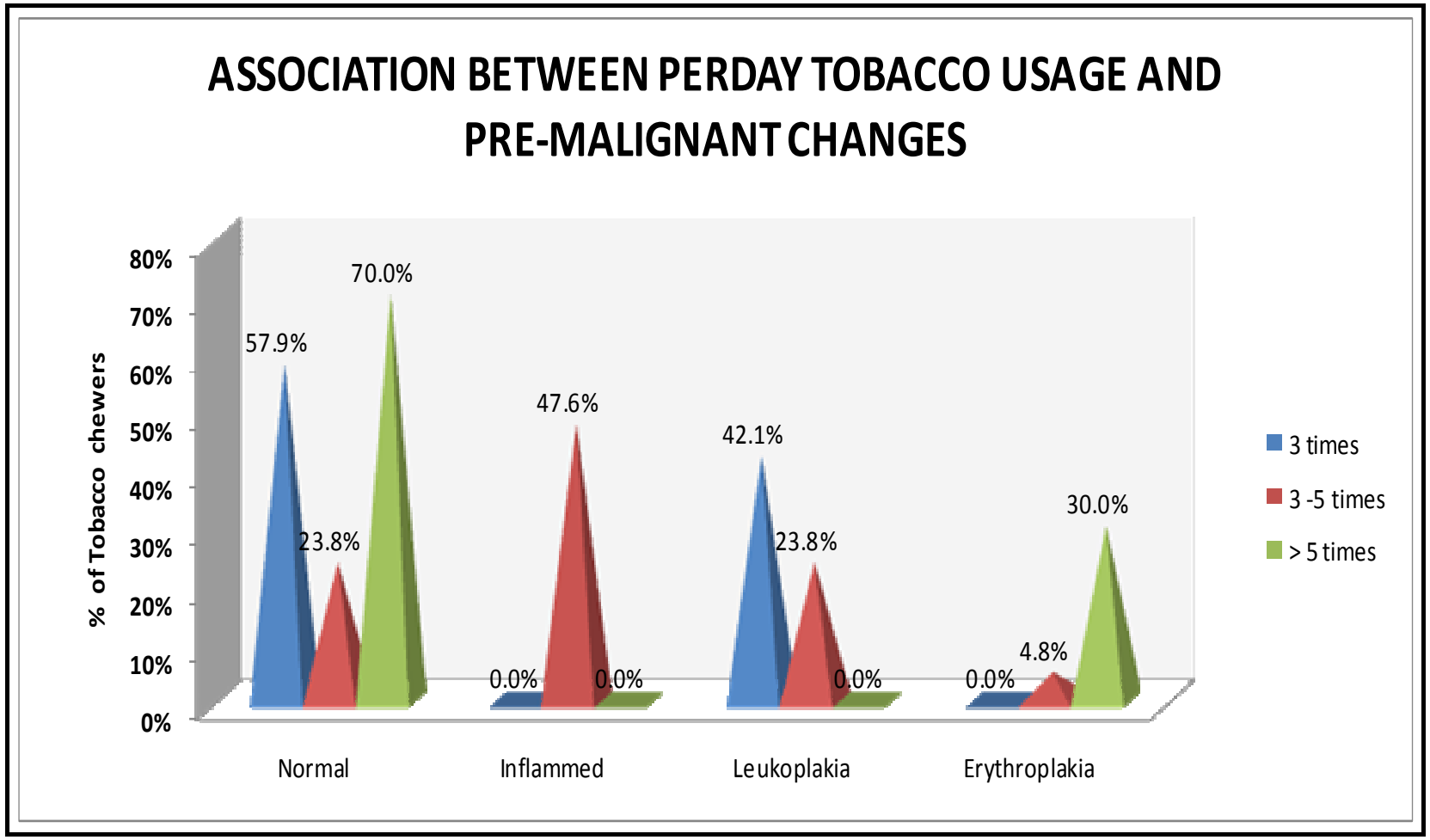

Figure 20: shows Association between perday Tobacco usage and pre-malignant changes

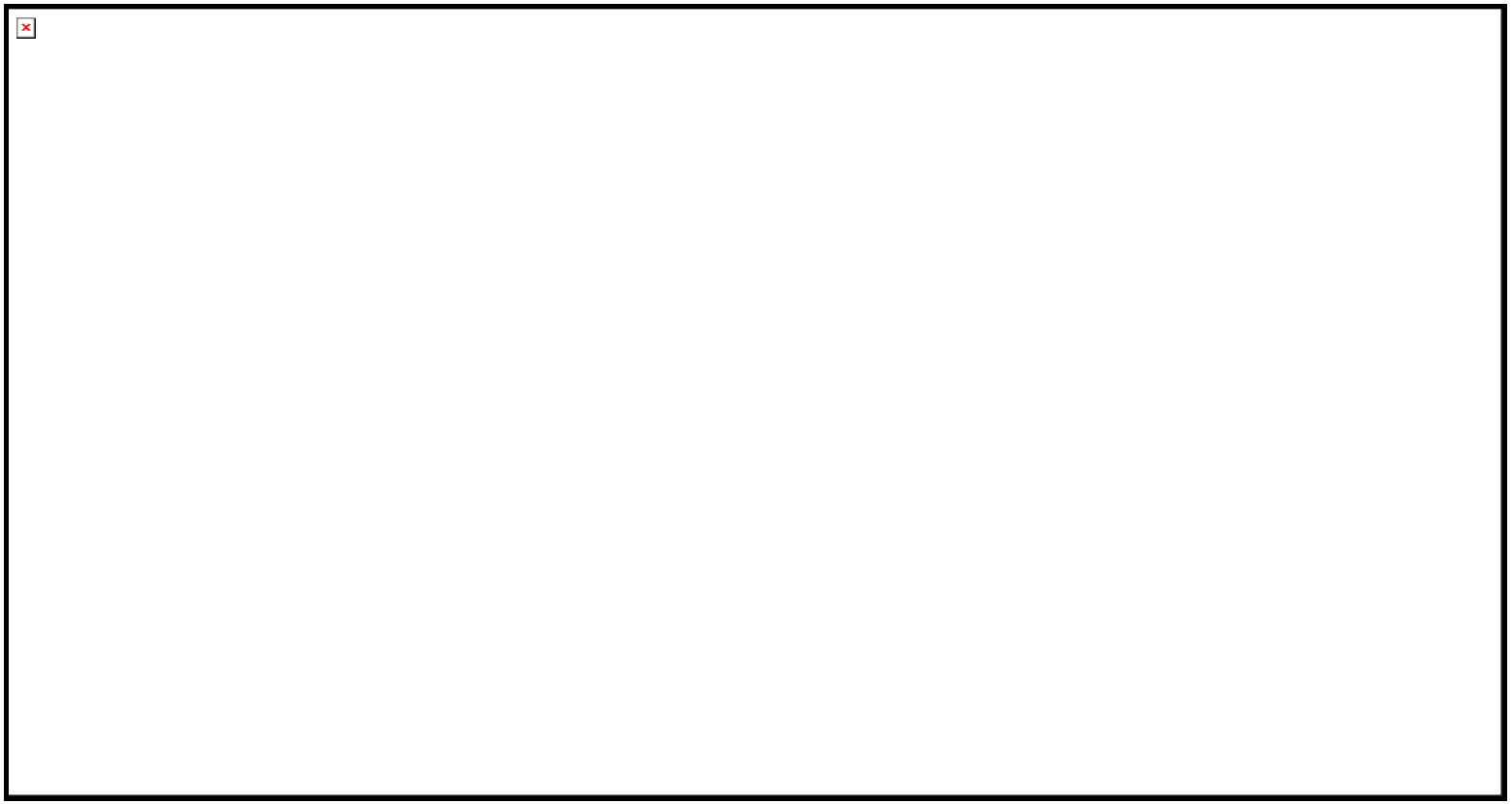

Figure 21: shows Association between smoking habit and pre-malignant changes

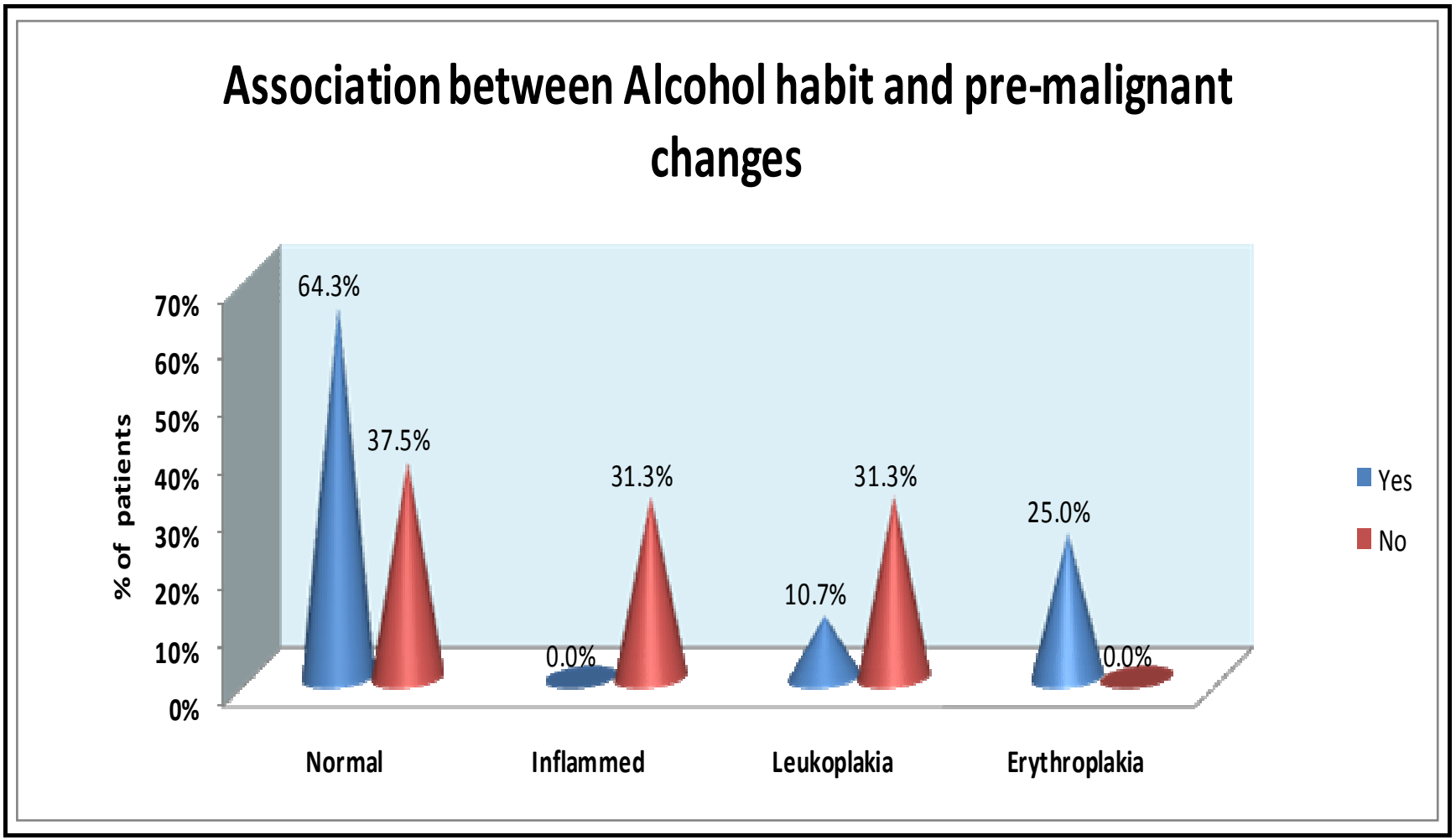

Figure 22: shows Association between Alcohol habit and pre- malignant changes

CHAPTER – V

DISCUSSION

"Discussion is an exchange of knowledge, arugment is an exchange of ignorance"

Robert Quillen

This study was conducted to identify the pre-malignant changes in oral mucosa among tobacco chewers by toludine blue test at medical wards at RGGGH, Chennai. The discussion of the study findings are presented in this chapter.

The discussion is based on the objects specified in the study

OBJECTIVES

1. To identify the changes in oral mucosa among tobacco chewers
2. To assess the oral mucosa after application of toludine blue among tobacco chewers.
3. To compare the effectiveness of changes in oral mucosa before and after the application of toludine blue among tobacco chewers.
4. To find out the association between the selected demographic variables and the effectiveness of toludine blue among tobacco chewers.

Review of literature facilitated the investigator to collect relevant information to support the study to design the methodology and to develop tools.

The sample size 60 people who were admitted in medical wards at RGGGH, Chennai. The cross sectional descriptive analysis.

CHARACTERISTICS OF DEMOGRAPHIC VARIABLES

Demographic information of tobacco chewers those who are participated in the study. It was seen that majority of the subjects are between 41-50 years of age and 58.3% are males and 81.7% are Hindus 83.3% are married and 55% are living in Nuclear family 33% are studied upto elementary education and 78.3% (47) their monthly income is less than Rs.1000/-

75% (45) of them are taking mixed diet and 20% (12) of them are vegetarian 11.7% of them are having the family history of cancer. 67% (40) of them are aware of oral cancer and 33% (20) of them are not aware of cancer. But only 5% (3) of them are aware of the cancer screening measures.

CHARACTERISTICS OF MEDICAL RELATED VARIABLES

Depicts that nearly 60% (36) subjects were having habit of tobacco chewing for more than 2 years and 25% (15) subjects were having 1-2 years and 15% (9) were more than one year of having habit of tobacco chewing.

41.7% (25) subjects were using pan parag and 40% (24) subjects were chewing tobacco 35%(21) were using the tobacco for 3-5 times per day and 33.3% (20) were using more than 5 times per day.

Associated factors like smoking is 55% (33) subjects were smoking and 60.6% (20) subjects were smoking 4-8 cigarretes per day. 46.7% (28) subjects having the habit of taking alcohol along with tobacco chewing.

The first objective is to identify the changes in oral mucosa among tobacco chewers.

The factors identified for the occurrence of Pre-malignant changes were demographic data, personal habits like tobacco chewing, pan parag, alcohol usage and smoking 67% of them had previous knowledge

regarding oral cancer and 33% of them were not aware of the oral cancer.

The demographic data analysis showed that most of the respondents were 41-50 years 33.3%, most of them were males 58.3%. Regarding the marital status most of them were married 83.3% living with there spouse and 55% of them were having urban family statistical significance was calculated by using chisquare test. Regarding religion majority of them who Hindu 81.7%, 1.7% Muslim and 16.7% were Christian.

Regarding the educational status 55% of them were finished elementary education and their occupationwas private 43.3% and unemployed was 43.3% and their monthly income was less than Rs.1000 was 78.3% most of the 51.7% were living in rural area and 48.3% were living in urban and they are taking mixed type of diet 75%.

Regarding the familiar history of cancer 88.3% was not having familial history and 11.7% are having family history of cancer and it was close relationship like father is 57.1% and brother was 28.6% and mother was 14.3% on the analysis of previous knowledge regarding cancer 67% of them who having some knowledge and 33% of them were not aware of cancer and most of them 38.3% were known about cancer by health care personnel.

Regarding the medical related information 60% of the people were having habit of tobacco chewing more than 2 years and 41.7% were using pan parag and 40% were having habit of chewing tobacco and 8.3% were using snuff and the tobacco usage per day is more than 3-5 times .35% were associated with smoking iand 55% were yes and 45% were not having habit of smoking. 60.6% were using 4-8 cigarettes/ day and regarding alcohol intake it was 46.7% and not using alcohol was 53.3%.

The clinical assessment in the pretest among premalignant changes in oral mucosa among tobacco chewers shows 100% of the tobacco chewers oral mucosa appears normal.

The second objective is to assess the oral mucosa after application of toludine blue among tobacco chewers.

Screening of the people the assessment of pre malignant changes in oral mucosa after application of toludine blue among tobacco chewers were having normal oral mucosa and 16.7% were having inflamed oral mucosa and 21.7% were having leukoplakia and 11.7% are having erythroplakia for the visual examination of the oral mucosa after the application of 1% toludine blue and 1% acetic acid by using aided magnification.

The third objective is to compare the effectiveness of changes in oral mucosa before and after the application of toludine blue among tobacco chewers.

Comparison of the effectiveness of changes in oral mucosa shows before the application of toludine blue all the tobacco chewers 100% were having normal oral mucosa. After the application of toludine blue only 50% were normal and 16.7% were inflamed, 1.7% has leukoplakia and 11.7% were having erythroplakia changes. This difference is statistically significant and it was calculated using chi-square test.

Difference between pretest and post test score was analysed using proportion with 95% confidence interval.

To find out the association between the selected demographic variables and the effectiveness of toludine blue among tobacco chewers.

This study shows that there was an association between demographic variables and pre-malignant changes in oral mucosa. Elders and males were having more changes than others. statistical significance was calculated using chi square test.

There was an association between pre-malignant changes in oral mucosa and their personal habits. Habit of using tobacco by chewing and smoking. Statistical significance was calculated using chi square test.

This study shows the association between pre-malignant lesion and their age and gender. Elders and males were mostly affected than others. Statistical significance was calculated using chi-square test.

According to the chi-square test there was no association between cancer related variables and pre-malignant changes in oral mucosa.

Tobacco related variables and pre-malignant changes in oral mucosa more time tobacco chewers, smokers and alcoholic persons were having m ore changes than others. statistical significance was calculated by chi-square test.

Regarding before application of toludine blue, visual examination of oral mucosa by magnifying lens, all the tobacco chewers were having normal oral mucosa. After application of 1% toludine blue, followed by 1% acetic acid, followed by 1% toludine blue. This difference was statistically significant and it was calculated using Chi square test and difference between pretest and post test score was analysed using proportion with 95% confidence interval and guidance 45%.

Warna kula suriya et. al., (2011) had conducted a study to determine cancer awareness among people of low-socio economic status in Mumbai slums. The study concluded that oral cancer creating awareness about screening its availability and motivating the general population for screening is necessary.

CHAPTER – VI

SUMMARY, RECOMMENDATION AND IMPLICATION

6.1 SUMMARY

A cross sectional descriptive study was conducted to identify the factors associated with occurrence of pre-malignant changes in the oral mucosa among tobacco chewers by the visual inspection by the application of 1% Toludine blue and 1% acetic acid. This study was based on Roy Adoptation Model

60 people were selected by convenient sampling technique and data were collected by using structured questionnaire. Descriptive and inferential statistics were used in data analysis.

The finding of the study includes the usage of tobacco chewers by the respondents. The factors identified and associated with demographic variables were age, gender, tobacco usage, chewing, snuff, smoking alcohol usage.

The characteristic of oral mucosa were identified by visual examination and it appeared normal in pre test for all the participants.

6.2 MAJOR FINDINGS OF THE STUDY

- Majority of the people were between 41-50 years of age and 58.3% of them more 81.7 of them were Hindus, 83.3% of them were married and 55% of them were living as a nuclear family.

- 55% of them have studied up to elementary education and 43% were working in private and 43% were unemployed of them are earning about < Rs.1000 per month are 78.3% and 51.7% were living in rural area and 75% of them are taking mixed type of diet.

- 11.7% of them are having the family history of cancer and 57.1% of fathers having family history of cancer 67% of them are aware of oral cancer and 33% of them have not aware of cancer. But only 3% of them having aware of the oral cancer screening measures.

- 60% of them are having habit of tobacco chewing for more than 2 years and 41.7% are using pan parag usage 35% of them were using tobacco usage per day is 3-5 times.

- 55% of them were having habit of smoking, 60.6% of them were smoking 4-8 numbers of cigarette per day and 39.4% of them were using 8-10 cigarettes per day, 46. 7% of them were taking alcohol while using tobacco.

- There is no association between the cancer related and pre-malignant changes in oral mucosa

- 50% of the people had positive for pre malignant changes in oral mucosa after application of 1% toludine blue and 1% acetic acid and 1% toludine blue and 50% of the people were negative for the visual examination of the oral mucosa after the application of 1% toludine blue and 1% acetic acid and 1% toludine blue by using aided magnification.

6.3 NURSING IMPLICATIONS

The study has implication for nursing practice, education, administration and research.

NURSING PRACTICE

- The nurse has a vital role in providing information for all people who are using tobacco.

- Awareness programmes regarding cancer screening programmes available at all health care centre including primary health centre.

- The nurse has to educated the people regarding the risk factors while using tobacco and to educate about screening programme and preventive measures.

- The study will be helpful for the nurse to educate the people regarding the treatment facilities available for the pre-malignant lesion.

NURSING EDUCATION

- In nursing curriculum general information about the cancer screening programmes.

- Nursing curriculum should emphasis on health education and counseling the people regarding the oral cancer screening

- Hence a holistic approach may be considered and reinforced among the people with regard to prevention of oral cancer

NURSING ADMINISTRATION

- All health care set up, primary health centres and sub-centres – nursing personal should be utilized for oral cancer screening programme.

- Mass media education on cancer screening should be broad casted regularly

- Community participation can be enhanced by utilizing self help group and other social welfare organization.

- Non governmental organization.

NURSING RESEARCH

- Nurses can be motivated to participate in counseling session for the people who are under going cancer screening
- The opportunities can be provided to the nurses to update the knowledge about cancer screening programme.

6.4 RECOMMENDATIONS FOR FURTHER STUDY

1. An awareness programme can be conducted in all institution and primary health centres regarding pre-malignant changes and the screening methods.
2. A study can be conducted to assess the stress level among people who are undergoing screening method.
3. The same study can be conducted on a large sample.
4. Mass health education programme to be given among people who are using tobacco in any manner, who are vulnerable to pre-malignant lesion.
5. A comparative study should be conducted with rural and urban population.
6. A study to assess the attitude of the people towards the oral cancer screening programme.

6.5 CONCLUSION

Oral health is essential in improving one's quality of life. Factors that influence the development of oral cancer include tobacco usage. oral cancer is preventable in an early stage. As the disease progresses the disability and quality of life deteriorate. Toludine blue test is a simple therapeutic modality which can be carried out in the primary health centre and is economical to identify pre-malignant changes. The present study shows that toludine blue test is more effective to identify pre-malignant changes in oral mucosa.

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TOOL FOR THE STUDY:

PART - A : DEMOGRAPHIC PROFILE

Sample no:

1. Age of the person

a) 18 - 30 years ☐ 31-40 years c) 4☐0 years ☐

d)51- 60 years ☐

2. Sex

a). Male ☐ Female ☐

3. Marital status

a) Married ☐ b) Unmarried ☐ c) Divorced / Separated ☐

d) Widower/widow ☐

4. Religion

a) Hindu ☐ b) Muslim☐ c) Christian ☐

d) Others ☐

5. Type of family

a) Nuclear ☐Joint c) Br☐ d) P☐ guest ☐

6. Educational status

a) Illiterate ☐ementary c) High☐condary ☐

d) Graduate and above ☐

7. Occupation

a) Government ☐ b) Private ☐

c) Pensioner ☐ d) Unemployed ☐

8. Income

a) <Rs 1000 / month ☐b) Rs 1000- 2000 / month ☐

c) Rs 2000- 5000 / month ☐ d) >Rs 5000 /month ☐

9. Area of residence

a) Rural ☐ b) Urban ☐

10. Dietary pattern

a) Vegetarian ☐ Non- vegetarian c) Mixed ☐

11.Familial History of cancer

a) yes ☐ b) No ☐

12. If yes, specify the relationship

a) Father ☐ b)Mother ☐ c)Brother ☐ d)Sister ☐

13. previous knowledge regarding cancer

a) Yes ☐ b)No ☐

14. If yes, specify

a)Mass media ☐ Friends ☐ elatives ☐
d)Healthpersonnel ☐

PART - B : MEDICAL RELATED INFORMATION

FACTORS ASSOCIATED WITH PRE-MALIGNANT CHANGES IN ORAL MUCOSA _DETAILS OF TOBACCO USAGE

1.Tobacco chewing

<1year ☐ >1year ☐ 1-2years ☐ >2years ☐

2.Manner of tobacco usage

Chewing ☐ Pan-parag ☐ Snuff ☐ Kanja ☐

3. Tobacco usage per day

3times ☐ 3-5times ☐ >5times ☐

4.Smoking

Yes ☐ No ☐

5.If yes, how many beedi/cigareete per day

4-8 numbers ☐ 8-10 numbers ☐ 10-20 numbers ☐ 3packet and above ☐

6.Alcohol intake

Yes ☐ No ☐

CHECK LIST TO ASSESS THE WOUND HEALING PROCESS

S.No	Item	Assessment	Score	Day 1	Day 5	Day 10	Day 15
1.	Size	• Length X width < 4 sq cm • Length X width < 4 - 16 sq cm • Length X width < 16.1 - 36 sq cm	**3** **2** **1**				
2.	Depth	• Tissues damaged but no break in skin surface. • Superficial, abrasion, blister or shallow crater. Even with, &/or elevated above skin surface (e.g., hyperplasia). • Deep crater with or without undermining of adjacent tissue.	**3** **2** **1**				
3.	Edges	• Not attached sides or walls are present; floor or base of wound is deeper than edge. • Rolled under, thickened soft to firm and flexible to touch. Indistinct, diffuse unable to clearly distinguish wound outline. • Attached even or flush with wound • Hyperkeratosis callous-like tissue formation around wound & at edges. • Fibrotic, scarredhard, rigid to touch.	**5** **4** **3** **2** **1**				
4.	Undermining	• Undermining < 2 cm in any area. • Undermining 2-4 cm involving <50% wound margin. • Undermining 2-4 cm involving >50% wound margin. • Undermining >4 cm in any area. • Tunneling and or sinus tract formation.	**5** **4** **3** **2** **1**				

S.No	Item	Assessment	Score	Day 1	Day 5	Day 10	Day 15
5.	Necrotic tissue type	• Non visible. • White / grey non – viable tissue and or non adherent yellow slough. • Loosely adherent yellow slough. • Adherent, soft, black eschar. • Firmly adherent, hard, black eschar.	**5** **4** **3** **2** **1**				
6.	Necrotic tissue amount	• Non visible. • < 25% of wound bed covered. • 25% to 50% of wound covered. • > 50% and < 75% of wound covered. • 75% to 100% of wound covered.	**5** **4** **3** **2** **1**				
7.	Exudate type	• None or bloody. • Serous: thin, watery, clear. • Purulent: thin or thick, opaque, tan/yellow. • Foul Purulent: Thick, opaque, yellow/green with odour.	**4** **3** **2** **1**				
8.	Exudate amount	• None • Scanty • Small • Moderate • Large	**5** **4** **3** **2** **1**				
9.	Skin colour surrounding the wound	• Pink or normal • Bright red and or blanches to touch. • White or grey pallor or hypo pigmented • Dark red or purple and or non blanchable	**6** **5** **4** **3**				

S.No	Item	Assessment	Score	Day 1	Day 5	Day 10	Day 15
9.		• Dark red blanchable • Black or hyper pigmented.	**2** **1**				
10.	Peripheral tissue edema	• Minimal swelling around wound. • Non pitting oedemaextends< 4cm around wound. • Non pitting oedema extends > 4cm around wound • Pitting oedema extends < 4cm around wound. • Crepitus and or pitting edema extends > 4cm	**5** **4** **3** **2** **1**				
11.	Peripheral tissue induration	• Minimal firmness around the wound. • Induration < 2cm around the wound. • Induration 2 – 4 cm extending < 50% around the wound. • Induration 2 – 4 cm extending >50% around the wound. • Induration > 4cm in any area.	**5** **4** **3** **2** **1**				
12.	Granulation tissue	• Skin intact or partial thickness wound. • Bright, beefy red; < 75% and > 25% of wound filled. • Pink, and or dull, dusky red and or fills < 25% of wound. • No granulation tissue present.	**4** **3** **2** **1**				
13.	Epithelialisation	• 100% wound covered, surface intact. • 75% to 100% wound covered. • 50% to 75% wound covered. • 25% to 50% wound covered. • <25% wound covered.	**5** **4** **3** **2** **1**				
SCORE			**60**				

INTERPRETATION:

S. NO.	SCORE	RESULT
1.	50 to 60	Very good
2.	40 to 49	Good
3.	30 to 39	Moderate
4.	20 to 29	Mild
5.	< 19	Poor

செவிலியர் கல்லூரி, சென்னை மருத்துவக் கல்லூரி
சமுதாய நேர்காணல் படிவம்

பகுதி-அ
சுய விவர கேள்வித்தாள்

மாதிரி எண்.:

1) வயது

அ) 18-30 வயது ☐

ஆ) 31-40 வயது ☐

இ) 41- 50 வயது ☐

ஈ) 51- 60 வயது ☐

2) பாலினம்

அ) ஆண் ☐

ஆ) பெண் ☐

3) திருமண விபரம்

அ) திருமணம் ஆனவர் ☐

ஆ) திருமணம் ஆகாதவர் ☐

இ) விவாகரத்தானவர் ☐

ஈ) துணையை இழந்தவர் ☐

4) சமயம்

அ) இந்து ☐

ஆ) கிறிஸ்துவர் ☐

இ) முஸ்லிம் ☐

ஈ) மற்றவர் ☐

5) குடும்பவகை

அ) தனிக்குடும்பம் ☐

ஆ) கூட்டுக்குடும்பம் ☐

இ) பிரிந்தகுடும்பம் ☐

ஈ) மற்றவகை ☐

6) கல்வித்தகுதி

அ) படிக்காதவர் ☐

ஆ) ஆரம்பக் கல்வி ☐

இ) உயர்கல்வி ☐

ஈ) கல்லூரி படிப்பு ☐

7) தொழில் விபரம்

அ) அரசு நிறுவனம் ☐

ஆ) தனியார் நிறுவனம் ☐

இ) ஓய்வூதியம் பெறுபவர் ☐

ஈ) வேலை இல்லாதவர் ☐

8) மாத வருமானம்

அ) ரூ.1000க்குள் ☐

ஆ) ரூ.1000- ரூ.2000 ☐

இ) ரூ.2000- ரூ.5000 ☐

ஈ) ரூ.5000க்கு மேல் ☐

9) வாழ்விடம்

அ) நகரப்பகுதி ☐

ஆ) கிராமப்பகுதி ☐

10) உணவு பழக்கவழக்கம்

அ) சைவம் ☐

ஆ) அசைவம் ☐

இ) இரண்டும் ☐

11) குடும்பத்தில் யாராவது புற்று நோயால் பாதிக்கப்பட்டுள்ளார்களா?

அ) ஆம் ☐

ஆ) இல்லை ☐

12) ஆம் எனில் உறவுமுறை

அ) தந்தை ☐

ஆ) தாய் ☐

இ) சகோதரர் ☐

ஈ) சகோதரி ☐

13) இதற்குமுன் புற்றுநோய் பற்றிய விபரம் தெரியுமா

அ) ஆம் ☐

ஆ) இல்லை ☐

14) ஆம் எனில் குறிப்பிடவும்

அ) தகவல் தொழில்நுட்பம் ☐

ஆ) நண்பர்கள் ☐

இ) உறவினர்கள் ☐

ஈ) மருத்துவ ஊழியர்கள் ☐

பகுதி-ஆ

மருத்துவம் சார்ந்த தகவல்

1) புகையிலை மெல்லும் பழக்கம்

அ) 1 வருடத்திற்கும் குறைவு ☐

ஆ) 1 வருடத்திற்கும் மேல் ☐

இ) 1-2 வருடம் ☐

ஈ) 2 வருடத்திற்கு மேல் ☐

2) புகையிலை உபயோகிக்கும் முறை

அ) புகையிலை மெல்லுதல் ☐

ஆ) பான்பராக் ☐

இ) பொடி போடுதல் ☐

ஈ) கஞ்சா ☐

3) ஒரு நாளைக்கு புகையிலை எத்தனை முறை உபயோகிக்கிறீர்கள்

அ) மூன்று முறை ☐

ஆ) 3-5 முறை ☐

இ) 5 முறைக்கு மேல் ☐

4) புகைபிடிக்கும் பழக்கம் உள்ளதா

அ) ஆம் ☐

ஆ) இல்லை ☐

5) ஆம் எனில் ஒரு நாளைக்கு எத்தனை பீடி/சிகிரெட் பிடிக்கிறீர்கள்

அ) 4 முதல் 8 வரை ☐

ஆ) 8 முதல் 10 வரை ☐

இ) 10 முதல் 20 வரை ☐

ஈ) 3 பாக்கெட்டுக்கு மேல் ☐

6) மதுப்பழக்கம் உள்ளதா

அ) ஆம் ☐

ஆ) இல்லை ☐

Lr.no. 276/CON/MMC/Chennai 3 dt 15.07.13

From

Mrs. R.Rama,
M.Sc(Nursing) II year,
College of Nursing,
Madras Medical College,
Chennai-3.

To

The Dean
Madras Medical College,
Chennai-03.

16/7

Through Proper Channel,

Respected Sir,

Sub: Requesting Permission to conduct a research study-reg

I, Mrs.R. Rama, studying M.Sc.Nursing II year ,College of nursing, Madras Medical college, kindly request you to grant me permission for the study proposed to conduct on the topic **"A study to identify the pre-malignant changes in oral mucosa among tobacco chewers by toluidine blue test at medical wards at Rajiv Gandhi Government General Hospital,Chennai-03. "** to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

Forwarded
15/07/13

Thanking you,

Date: 15.07.13

Place: Chennai-03

Yours obediently,

R.Rama

(R.Rama)

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

EC RegNo.ECR/270/Inst./TN/2013
Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
R.Rama,
M.Sc.,(N) II year,
College of Nursing,
Madras Medical College, Chennai-3.

Dear R.Rama

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "A Study to identify the premalignant changes in oral mucosa among tobacco chewers by toludine blue test at medical wards at Rajiv Gandhi Government General Hospital, Ch.03" No.02072013.

The following members of Ethics Committee were present in the meeting held on 06.07.2013 conducted at Madras Medical College, Chennai -3.

1. Dr.G.SivaKumar, MS FICS FAIS --- Chairperson
2. Prof. R. Nandhini MD -- Member Secretary
   Director, Instt. of Pharmacology ,MMC, Ch-3
3. Prof. Shyamraj MD -- Member
   Director i/c , Instt. of Biochemistry , MMC, Ch-3
4. Prof. P. Karkuzhali. MD -- Member
   Prof., Instt. of Pathology, MMC, Ch-3
5. Prof. Kalai Selvi -- Member
   Prof of Pharmacology, MMC, Ch-3
6. Prof. Siva Subramanian, -- Member
   Director, Instt. of Internal Medicine, MMC, Ch-3
7. Thiru. S. Govindsamy. BABL -- Lawyer
8. Tmt. Arnold Saulina MA MSW -- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nandini
Member Secretary, Ethics Committee

CERTIFICATE OF CONTENT VALIDITY

This is to certify that a tool prepared by Mrs. R.Rama, M.Sc. Nursing, II year of College of Nursing, Madras Medical College, undertaking a research study on "A study to identify the pre-malignant changes in oral mucosa among tobacco chewers by toludine blue test at medical wards at Rajiv Gandhi Government General Hospital, Chennai - 03", has been validated by me and is found to be valid and up to date and she can proceed with this tool to conduct the main study.

Signature :

Name :

PRINCIPAL
MADHA COLLEGE OF NURSING
MADHANAGAR, KUNDRATHUR
CHENNAI - 600 069
PHONE: 24780736

Designation :

Date :

Place :

Seal :

CERTIFICATE OF CONTENT VALIDITY

This is to certify that a tool prepared by Mrs. R.Rama, M.Sc. Nursing, II year of College of Nursing, Madras Medical College, undertaking a research study on "A study to identify the pre-malignant changes in oral mucosa among tobacco chewers by toludine blue test at medical wards at Rajiv Gandhi Government General Hospital, Chennai - 03", has been validated by me and is found to be valid and up to date and she can proceed with this tool to conduct the main study.

Signature : 31/8/13

Name : DIRECTOR AND PROFESSOR
Institute of Internal Medicine
Madras Medical College,
Govt. General Hospital,
Madras-600 003.

Designation :

Date :

Place :

Seal :

Lr.No. 276/ CON/ MMC/ Chennai-3 dt 15.07.13

From

Mrs. R. Rama,
M.Sc(Nursing) II year,
College of Nursing,
Madras Medical College,
Chennai-3.

To

The Professor and HOD,
Institute of Internal Medicine
Rajiv Gandhi Government General Hospital,
Chennai-03.

Permitted
Work
25/7/13

Through Proper Channel,

Respected Sir,

Sub: Requesting Permission to conduct a research study-reg

I, Mrs.R.Rama, studying M.Sc.Nursing II year ,College of nursing, Madras Medical college, kindly request you to grant me permission for the study proposed to conduct on the topic **"A study to identify the pre-malignant changes in oral mucosa among tobacco chewers by toluidine blue test at medical wards atRajiv Gandhi Government General Hospital,Chennai-03."** to fulfill the requirement of data collection. I assure you that it will not interfere with routine activities of the study settings.

Forwarded
15/7/13

Thanking you,

Date: 15.7.13

Place: Chennai-03

Yours obediently,

R. Rama

(R. Rama)

CERTIFICATE OF ENGLISH EDITING

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the Dissertation Topic **"A Study to Identify Pre Malignant Changes in Oral Mucosa among Tobacco Chewers by Toludine Blue Test in Medical Wards at Rajiv Gandhi Government General Hospital, Chennai-03"** done by Mrs.R.Rama, M.Sc (N), II Year, College of Nursing, Madras Medical College, Chennai – 03 has been edited for English Language appropriateness.

Date : 06. 02. 2014

Place: Chennai – 03.

(M. Gokul Praveen Babu, M.A)
Assistant Professor,
Department of English,
Tagore College of Arts and Science,
Chrompet,
Chennai – 44.

(M. Gokul Praveen Babu, M.A)
Assistant Professor,
Department of English,
Tagore College of Arts and Science,
Chrompet, Chennai - 44.